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IMPLEMENTING THE MEDICARE PRESCRIPTION DRUG BENEFIT AND MEDICARE ADVANTAGE PROGRAM: PERSPECTIVES ON THE PROPOSED RULES

HEARING

BEFORE THE

COMMITTEE ON FINANCE
UNITED STATES SENATE

ONE HUNDRED EIGHTH CONGRESS

SECOND SESSION

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IMPLEMENTING THE MEDICARE PRESCRIPTION DRUG BENEFIT AND MEDICARE ADVANTAGE PROGRAM: PERSPECTIVES ON THE PROPOSED RULES

TUESDAY, SEPTEMBER 14, 2004

U.S. SENATE,
COMMITTEE ON FINANCE,
Washington, DC.

The hearing was convened, pursuant to notice, at 10:05 a.m., in room S–215, Dirksen Senate Office building, Hon. Charles E. Grassley (chairman of the committee) presiding.

Also present: Senators Nickles, Thomas, Santorum, Frist, Smith, Baucus, Breaux, Graham, Bingaman, and Lincoln.

OPENING STATEMENT OF HON. CHARLES E. GRASSLEY, CHAIRMAN, COMMITTEE ON FINANCE

The CHAIRMAN. Good morning, everybody. We are back in business, I can tell, from the long lines out in the hall of people waiting to come to hearings.

And, of course, this hearing is a very important one as well because we are looking at the proposed rules that were issued last month by Centers for Medicare and Medicaid Services to implement the prescription drug benefit and the Medicare Advantage program established by the Medicare Modernization Act.

Last year, members from both sides of the aisle devoted countless hours to make the prescription drug benefit, an improved program, reality, rather than the wishful thinking and political promises that it was for several years. And we did this for 40 million Americans, seniors, and those who have disabilities, and all of these people depending upon Medicare.

After years of promising to get it done, last year we finally did get it done and everybody here present played a very important role in accomplishing that, and doing it in a bipartisan way.

For the first time, Medicare will offer voluntary prescription drug benefits to all seniors in the year 2006. Beneficiaries also will have more coverage choices. If beneficiaries like the coverage that they have, they can keep it.

A number of beneficiaries told me that they are completely satisfied with their Medicare that they have already had, or know that they are going to get. They are telling me that they want to stay in fee-for-service Medicare, and that is just exactly some of the choices that we want people to be able to make.

In fact, Congress, in the Modernization Act, took steps to make sure that beneficiaries across the Nation have good access to physician services in fee-for-service. We had been hearing, over the past few years, that beneficiaries were finding it harder and harder to find a doctor who would see Medicare people.

We canceled, for instance, a 4.5 percent physician payment cut that would have taken effect next year. Both Republicans and Democrats worked to prevent the payment cut, because if beneficiaries cannot find a doctor, then Medicare benefits would be meaningless.

So we are here today because the Centers for Medicare and Medicaid Services have issued the proposed rules for implementing the new drug benefit and the expanded Medicare coverage options. These proposed rules bring the Nation's Medicare beneficiaries an important step closer to having a much-needed affordable prescription drug benefit and a new coverage choice.

Plain and simple, Medicare has crossed, then, a milestone, really the first important one since it was adopted 38 years ago. Under the proposed rule, about one-third of all Medicare beneficiaries will be eligible for low-income assistance, meaning that they will have drug benefits with no gap in coverage, and limited or no premium deductibles or cost sharing. For these beneficiaries, the drug benefit will cover as much as 85 to 98 percent of their drug costs.

Now, one area that we will hear about today is the retiree drug subsidy. Employers provide coverage on a voluntary basis, and it is sorely evident that they are finding it harder and harder to continue.

From 1991, long before our bill's enactment, the number of large employers offering health coverage to their retirees dropped 25 percent, from about 80 percent to 61 percent of the companies in 2003.

Our new legislation sought to stem this alarming trend by providing $89 billion in direct subsidy and tax benefits to protect retiree health coverage. This funding makes it more likely, not less likely, that the employer will continue retiree benefits.

At the same time, I want to ensure that the direct subsidy and tax benefits provided are monitored closely. We must ensure that we maintain the utmost level of integrity in the implementation of this program.

Both the Department of Justice and the Department of Health and Human Services Office of Inspector General have expressed strong concern with regard to this provision. Therefore, ensuring that only those employers who actually continue retiree health coverage receive the subsidy will be critical.

Another issue that I am sure we will hear about today is the region size of the Medicare Advantage regional preferred provider organizations. PPOs are among the most popular coverage options for other Americans.

About half of the Americans with private insurance are enrolled in PPOs. But private plan options are not widely available to Medicare beneficiaries. Where private plans are available, they are very popular.

Iowa beneficiaries who have joined a plan have told me that they like their plans. The Medicare Advantage regional plans will give

beneficiaries more coverage choices by requiring plans to serve both urban and rural areas, the entire region.

Beneficiaries deserve choices between regular Medicare and other options that can offer them better coordinated care and additional benefits, such as 24-hour consulting nurse services. These services can be very valuable, particularly for beneficiaries with chronic conditions.

Congress also included numerous beneficiaries protections in the new drug benefit. Rules and requirements about prescription drug formularies are among the most important protections because beneficiaries must be assured that they can get the coverage for the drugs that their doctors prescribe.

The U.S. Pharmacopoeia has developed draft model guidelines for drug classes and categories to provide a framework for plan drug formularies, and CMS has additional oversight authority to make sure the plans do not use particular formulary designs to game the system by discouraging sicker people from enrolling.

Again, I know that issues relating to formulary design have engendered very serious debate in the last couple of months, and I am looking forward to hearing our witnesses' perspective on the Pharmacopoeia draft guidelines and the proposed rules.

And by the way, we have Dr. McClellan at the table. I want to recognize you and your staff for your dedication and effort. CMS faced an enormous task in developing these rules. You just really took the helm of CMS just a few months ago, but under your leadership, CMS has tackled this enormous task with gusto.

And I compliment you for that, because you deserve credit for getting these rules out just 8 months after the President signed the bill, an incredible accomplishment.

Now, today I am looking forward to an informative and insightful hearing. Of course, it is the political season and some may not be able to pass up the opportunity to take some political pot-shots. It is always much easier to tear something down than to build something up.

In the June drug card hearing, I quoted Bob Ball, former Commissioner of Social Security, who was involved in getting Medicare up and running 38 years ago. He said, "To a remarkable degree, opponents, as well as supporters of Medicare, tried hard to be helpful." Those words that were so relevant 40 years ago are equally relevant today.

I look forward to the hearing, and now I call on Senator Baucus.

OPENING STATEMENT OF HON. MAX BAUCUS, A U.S. SENATOR FROM MONTANA

Senator BAUCUS. Thank you very much, Mr. Chairman. This is a very important hearing. We are trying to determine how well CMS is doing its job in issuing regulations implementing the very important law. I suspect there will be many other hearings in addition to this one, but this is important.

Before I begin, however, I would like, Mr. Chairman, to say that Senator Rockefeller very much wishes he could be here. He, however, is very involved in the Porter Goss Intelligence Committee confirmation hearing.

He has a lot of questions, as you might guess. He hopes that the witnesses would answer all of those questions in a very timely manner.

[The questions appear in the appendix.]

Senator BAUCUS. As we know—I think it is important to remind us, though—that when Congress passes a law, it is up to the executive branch to write regulations and implement it, with the caveat that it is according to Congressional intent.

Today we will hear about implementation of the 2003 Medicare law and we will get a progress report on the 2,000 pages of proposed regulations for the new law. Somebody showed me the book, Mr. Chairman. I think Title 1 is like this, and Title 2 is a little smaller. But it is a huge volume, lots of pages, and I expect there will be more. It is a lot of work. I applaud Dr. McClellan and CMS for your hard work in producing this.

I must say, though, I think there are a lot of holes here. There are a lot of gaps. I am disappointed with the lack of guidance, for exmaple, in a lot of the regulations. I think guidance is very important for providers, for beneficiaries, for employers, for all involved, and especially taxpayers. But there is not, in my judgment, adequate guidance in a lot of areas.

For example, what will CMS do to prevent large corporations from getting an unjustified windfall by reducing retiree drug benefits? The Chairman mentioned it. I think most of us on the committee are very concerned about that, certainly those of us who worked so hard to write this legislation and were involved in conference. It is a big issue. It is not an easy one to solve. There is a lot of tension between employers, on the one hand, and beneficiaries on the other.

But there needs to be much more guidance to be fair to everyone involved and not allow this windfall. As I said, I strongly support incentives to prevent employers from dropping retiree coverage. I think that is very important.

I think the employer subsidy was essential to getting the bill passed, as you well know. But while employers should be encouraged to continue to do the right thing, they should not be rewarded for cutting retiree drug benefits.

Even if you, Dr. McClellan, and CMS find an acceptable standard for defining actuarial equivalence—I am not sure that it is there yet—my question is, how will CMS ensure that employers meet that standard?

There is another area where I would like to have seen more details and more guidance, and that is the criteria for turning down a plan's application to participate as a prescription drug plan or a Medicare Advantage plan. I say that because, in implementing the drug discount card, CMS appears to have accepted all comers.

In my State of Montana, for example, there are 41 different drug cards, in other States, many more. I just think there are too many choices. People are very confused. I think that is one reason why the discount card has not enjoyed the success that we may have hoped that it would.

I hope that CMS will exercise more discretion in reviewing applications for drug plans. There have to be tighter standards. I would like to know more about what factors might influence a decision to

turn down a plan. The proposed rule does not provide much guidance in that area.

Finally, one of the biggest questions left unanswered is this. What will the regions be for Medicare preferred provider organizations and prescription drug plans? How big will they be? The big debate, as you well know, in the conference on this question, essentially Congress punted the problem to CMS.

But, still, Congress cannot write every detail, every jot and tittle. Sometimes you have got to implement some of this to an agency, and you are the agency that we gave the instructions to.

But, nevertheless, there is no guidance here. There is no real indication of what CMS will do and how it is going to implement that decision as to the size of the regions. I know the health plans have urged you to adopt the State-based regions. It is in their interests.

But last fall, I would remind you, the administration argued that the best way to ensure that PPOs can serve rural areas, particularly in States like mine and that of the Chairman, would be to create large regions encompassing several States and to require these plans to cover the entire region. The proposed regulations do not indicate how you are going to deal with that.

Given all the extra money, and I might say, some might argue wasteful amounts of money that Medicare will pay PPOs to come to rural America, I, for one, would be more than a little bit disappointed if they do not.

These, and many other areas, are very important as you prepared to enroll millions of seniors in Medicare drug benefits starting in 2006. To that end, I should say that I hope that millions will enroll. I hope that the recent disappointing experience with the Medicare drug discount card does not portend seniors' response to the new drug benefit in 2006.

I have mentioned this, and I will say it again. Montana's seniors have reacted very coolly to the drug card. They are unimpressed with the level of discounts. They are confused by the number of choices. The vast majority of Montanan seniors have chosen not to enroll in the drug card.

I hope that the drug card experience does not sour participation in the actual Medicare drug benefit, and I hope that CMS has learned a lot from the problems that have resulted in implementing the drug discount card so that the drug benefit enjoys much better success.

I voted for the new Medicare law. Although it is not perfect, I think it holds the promise of providing a long overdue prescription drug benefit to millions of elderly and disabled Americans, with comprehensive coverage for those of modest means.

But if the law is not implemented fairly, I will not continue to support it. A lot rides on how CMS carries out the law. I appreciate the work that CMS has done to write the regulations and implement the new law, but if we want beneficiaries to participate in this benefit we must convince them that the benefit will actually help them. So far, I think most seniors remain unconvinced.

Before I close, though, I would like to comment on another, related topic. Mr. Chairman, as you know, it is very important that this committee remain vigilant in its oversight of the new Medicare

law's implementation—I commend you for holding this hearing—and to make sure that CMS follows the law.

But in a few days, GAO will issue a report that I requested last year about the PPO demonstration that CMS established in 2001 and 2002. In many respects, that demonstration was the precursor to some of the private plan provisions that were ultimately enacted in the new Medicare law.

I understand that GAO will find that CMS exceeded its legislative authority to encourage PPOs to participate in that demonstration. This is very troubling. Dr. McClellan, I know that CMS did not implement this PPO demonstration under your watch, but this committee must ensure that the agency follows the law in implementing this new and important legislation.

I look forward to discussing that report when it is made public.

Thank you, Mr. Chairman. I look forward to our witnesses' testimony.

The CHAIRMAN. Yes. Thank you very much.

Since Dr. McClellan needs no introduction—I have already complimented you for the work that you have done on these regulations—we would hear your testimony and then go to questions.

STATEMENT OF HON. MARK B. McCLELLAN, M.D., Ph.D., ADMINISTRATOR, CENTERS FOR MEDICARE AND MEDICAID SERVICES, WASHINGTON, DC

Dr. MCCLELLAN. Thank you, Mr. Chairman, Senator Baucus, and distinguished members of this great committee. Thanks for inviting me here today to discuss the most important enhancements of Medicare since it was created in 1965.

I especially want to thank all of the committee members and your staffs for your hard work on the Medicare Prescription Drug Improvement and Modernization Act of 2003, and your support for CMS as we work to implement this important new law as effectively as possible.

Thanks to your efforts, we are providing overdue benefits for the Nation's seniors and people with disabilities, including, for the first time in Medicare, coverage for outpatient prescription drugs.

The MMA provides many other modernizations, ranging from better preventive benefits, to new quality improvement programs, and greater access to disease management services so the beneficiaries can lower their out-of-pocket costs and enjoy better health at the same time.

Altogether, there are hundreds of distinct provisions. Of those with effective dates prior to August 31 of this year, CMS has completed 91 percent, with the remaining few in progress.

Accomplishing so much in such a short time reflects the hard work of the dedicated CMS staff, and many evenings and weekends. It also reflects new steps that we are taking to make sure our agency has the structure, the tools, and the personnel needed to meet our expanded mission.

We know we have got a lot more to do, both to implement the benefits effectively, and to make sure our beneficiaries get the facts and the help they need to get the most out of these new benefits.

Our analysis of the impact of these new benefits shows just how important it is. For a typical Medicare beneficiary, the new vol-

untary Medicare drug benefit will cover 53 percent of drug costs. For someone without coverage today, that means total spending on drugs will fall by nearly $1,300.

The savings for the standard drug benefit come from two main sources. First, beneficiaries who enroll in a Medicare drug plan will get the best possible negotiated price discounts on the drugs they purchase.

With clear information about drug prices and benefits, beneficiaries will be able to choose the plan that gives them the best coverage for the drugs they need rather than a take-it-or-leave-it formulary that may not meet their needs.

This transparency and choice is expected to reduce drug payments by an average of 15 percent initially, rising to 23 percent within 5 years. That is even accounting for the fact that lower prices, plus coverage, means that many beneficiaries will have access to drugs that they could not afford before, and will use more as a result.

Our approach is expected to provide the best discounts on drugs, discounts as good or better than could be achieved through direct government negotiation. We expect prices that will be substantially lower than Medicare's prior experience with price regulation for the drugs that it currently covers under Medicare Part B.

In fact, competition has lowered drug prices already in the Medicare prescription drug discount card program where numerous independent studies have found real savings available right now, with discounts of over 20 percent on brand-name drugs, according to the Kaiser Foundation, and prices that are lower than Medi-Cal prices, the Medicaid prices in California, according to Consumers Union.

These price reductions are on very broad formularies of drugs that beneficiaries commonly use, including many drugs not included in the formularies of government-run drug plans. We expect to build on these savings for the drug benefit.

The second way that the drug benefit will offer savings to Medicare beneficiaries is through the new Medicare subsidy of 75 percent of costs of the coverage. We expect that, in 2006, Medicare will pay about $105 per month for each enrolled beneficiary, and the beneficiaries will pay a monthly premium of around $35 for standard drug coverage.

With this coverage in 2006, beneficiaries enrolling in the standard benefit will pay an annual deductible of $250, plus 25 percent of their drug costs, up to an initial coverage limit of over $2,000, between $2,000 and $250, to be exact.

After that, once the beneficiary reaches $3,600 in out-of-pocket spending, the Federal Government, through Medicare, will pay, and the plans will pay, about 95 percent of the beneficiary's further drug costs, and this coverage will never run out.

Medicare's oversight of formulary classes and drug coverage and payment tiers, utilization management, and other key features of the drug benefit will assure that all beneficiaries have access to the medicines that they need at an affordable price.

The subsidy Medicare provides for standard drug coverage can be combined with other sources of assistance to provide even more generous coverage. The State prescription assistance programs,

charitable organizations, and other individuals can contribute to beneficiary out-of-pocket costs and have those contributions count as true out-of-pocket expenditures that trigger the catastrophic coverage. Employers and unions, as Senator Baucus mentioned, will obtain a subsidy for payments they make towards covering retirees.

The new drug benefit will lead to significantly greater support for retiree coverage. We intend to maximize the improvements in coverage for retirees by providing multiple ways for employers to offer high-quality coverage at a lower cost. Employers can receive a retiree drug subsidy for their own comprehensive coverage.

They can wrap around Part D drug coverage like they do for other Medicare benefits to provide comprehensive coverage, and they can offer coverage through a Medicare Advantage plan for their retirees. In all of these approaches, there will not be any employer windfalls. All Medicare payments must go to the retiree coverage.

One of the major points I want to emphasize is the comprehensive prescription drug assistance available from Medicare to many beneficiaries with limited means, beneficiaries who, until this law, have struggled for too long between paying for drugs and paying for other basic necessities like food and rent. Altogether, about a third of our beneficiaries are eligible to get coverage that will take care of 95 percent or more of their drug costs, on average.

In addition, because of the high value of this new drug benefit and our unprecedented outreach efforts, in collaboration with the Social Security Administration to get people enrolled, we expect to attract more than a million beneficiaries with limited means who are eligible for, but have not previously enrolled in, Medicaid, to get more help, such as payment of their Medicare premiums in full.

The Medicare Modernization Act requires us to use an asset test to target this comprehensive help to where it is most needed. I want to be clear that this straightforward asset test does not count items such as the family home or household goods, or personal effects such as a wedding ring, a vehicle, a burial plot, and many other types of resources.

The straightforward asset test will count only liquid assets like stocks and bonds and savings accounts, plus real estate holdings other than the primary residence. We have also provided a method for verifying income and resources that would eliminate the need for extensive paper documentation.

While many of these Medicare improvements will not take effect until January 1, 2006, beneficiaries will have new opportunities to lower their medical costs in 2005. Medicare will provide the most comprehensive set of preventive benefits ever, including screening tests for heart disease and diabetes for the first time.

We will also start to provide chronic care improvement services at a lower cost and improved quality for beneficiaries with chronic illnesses, and the drug card will continue to provide savings on drugs.

And we expect more beneficiaries to have access to better prevention benefits, disease management services, and even drug benefits through Medicare Advantage plan expansions in 2005.

Greater access to better benefits and lower costs in Medicare Advantage is a direct result of the Medicare Modernization Act and provisions that had strong bipartisan support.

For a typical beneficiary, this option means a lot of savings. On average, beneficiaries in Medicare Advantage spend nearly $700 less than beneficiaries enrolled in fee-for-service Medicare out of their own pockets. Beneficiaries in poor health who are enrolled in a Medicare Advantage plan experience out-of-pocket savings of over $1,600, compared to fee-for-service beneficiaries who have poor health and Medigap coverage. That is a savings of nearly $140 a month.

Much lower out-of-pocket costs are not the only benefit of being enrolled in Medicare Advantage. Coordination of care, special disease management programs for people with chronic illnesses, enhanced benefit packages including drugs, eyeglasses, and other services not covered by Medicare are available to more and will be used by more beneficiaries in 2005 as a result of Medicare Advantage.

In 2006, we expect to make more affordable comprehensive care options available to all Medicare beneficiaries through regional PPO plans. This is the most popular type of health plan in the country and our beneficiaries will finally be able to get it wherever they live.

We are closer than ever to providing better benefits, including drug coverage, in an up-to-date Medicare program. Right now, we are seeking input to make sure we provide these benefits as effectively as possible, so we are taking steps like augmenting our normal public comment process with a series of public meetings for discussion of many critical topics.

By working together and hearing from all perspectives, we intend to do all we can to bring the best possible Medicare improvements forward at the lowest possible cost.

I thank the committee for its time and I would welcome any questions that you all may have.

[The prepared statement of Dr. McClellan appears in the appendix.]

Senator FRIST. Dr. McClellan, thank you very much. I apologize for being a little bit late. I had just opened the U.S. Senate. But I appreciate your comments.

This hearing is an important hearing and one that is going to be instructive for all of us to get a current feel for where we are today, and hopefully make recommendations, and through our questioning, express issues that are of concern to us and concern to our constituencies.

A lot of the health care issues will inevitably be involved in the political arena that is out there. I think one of our goals needs to be to really stay on these very important issues and implementing a program and a plan that is very important to the 45 million people who are benefitting, and will benefit increasingly, and also those future generations.

A couple of issues I want to address right up front. They are both issues that likely will come up again in other questions. One has to do with the increase in the Part B premiums, and the other is

with the USA Today article that I would like to at least begin to get your comments on as well.

First of all, the Part B premiums, as we all know, is a formula that was passed in 1997 in terms of the formula itself. There have been accusations that the President is responsible for this formula. It is clear among us, because I believe everybody on this committee, except for Senator Lincoln because she was not here at the time, voted for that 1997 bill that had the formula in it.

Essentially, as I understand it, and I am going to ask you to comment further on it, CMS calculates the cost of Medicare's Part B program for the following year. The formula itself that CMS uses to determine the premium that seniors must pay for these Part B benefits, including physician services, is driven by the formula.

The government pays for 75 percent of those costs and passes on 25 percent of the costs to the seniors in the form of premiums. If the costs go up in this Part B program, that is, principally in physician services, premiums go up automatically.

My first question. I first will make the statement that we all voted for it in 1997, and it is a formula that is there. The first question is, is the description I gave essentially accurate, and would you like to add anything to that?

Dr. MCCLELLAN. That description is exactly right, Dr. Frist. The only thing I would like to add, is that the premium also makes sure that we have a reserve in the Part B trust fund to make sure that we have got adequate funds available to pay, and a little bit of the funding goes into that as well.

But the main purpose of our statutory structure for Part B is to make sure that beneficiaries get strong support from the Federal Government, 75 percent support, for the costs of receiving their benefits, and they are getting more benefits than ever in 2005.

Senator FRIST. And we are talking about physician services. Drug benefits are in a separate category. I say this because people are kind of throwing everything in together. So the second part of that question is, the new Medicare prescription drug program will be offered under Part C and Part D. Is that not true, the new drug part?

Dr. MCCLELLAN. The new drug benefit is a completely voluntary, separate benefit. You can sign up for it or not, if you want, in 2006. The Part B premium, in Part B, is not connected to that at all. The costs and the benefits provided in Part B, as you said, are for physician services, hospital outpatient services, other critical services, but not prescription drugs.

Senator FRIST. So is it correct to say that the new drug benefit did not affect these proposed Part B premium increases for 2005?

Dr. MCCLELLAN. That is correct.

Senator FRIST. The third issue is physicians, since we are talking about physician services and payments. All of us have experiences with the fact that physicians, if they are not adequately compensated, are just not going to be able to participate in the Medicare program.

Before we passed the Medicare Modernization Act, doctors faced a 4.5 percent cut in Medicare payments, both in 2004 and 2005. The bill that we passed did reverse those cuts and it gave doctors a 1.5 percent increase for 2004 and 2005.

First of all, is that correct in terms of what we did for physicians in this bill?

Dr. MCCLELLAN. That is correct. As you may recall, at the time there were a lot of concerns from physicians around the country and their patients about continued access to physician services.

I think that is why there was such strong bipartisan support for increasing the payments to physicians rather than letting a 4.5 percent payment reduction in 2004, and then another 4.5 percent payment reduction in 2005, go into effect.

Senator FRIST. And so we are talking about physician services. We are talking about the bipartisan support for keeping physicians adequately compensated so that they are able to deliver care to 45 million individuals with disabilities and seniors.

What I wanted to do, is make sure that people understand the bipartisan support for those physician services. In fact, I would like to place into the record two letters. The first, dated September 30, 2003, was signed by 18 of my Senate colleagues—and I should add, including Senator Kerry—that asks that the final Medicare bill include "a meaningful increase" in funding for private Medicare health plans in 2004 and 2005.

And the second letter is dated May 25, 2004, signed by 73 of our Senate colleagues, including Senator Kerry, and it states support for the provisions of the Medicare Modernization Act preventing cuts in physician reimbursement.

[The letters appear in the appendix.]

Senator FRIST. I know we will probably end up coming back to the premium increases, but I wanted to at least get the lay of the land set up.

The second question, and I will be very brief, is from an article that was brought up on the floor of the U.S. Senate a few minutes ago, and therefore I know it is inevitable that it will come up today.

An article in USA Today this morning claims that a "typical 65-year-old can expect to spend 37 percent of his or her Social Security income on Medicare premiums, co-payments, and out-of-pocket expenses in 2006. That share is projected to grow to almost 40 percent in 2011, and nearly 50 percent by 2021."

I am not sure if you have even seen the article, but since it came up on the Senate floor, I would like for you to at least to comment. Is that accurate? How do you respond to the report?

Dr. MCCLELLAN. Well, I have seen it. In fact, we gave Congressman Stark the information several months ago that was the basis for this chart. I have also had a chance to discuss this with our independent CMS actuaries.

What they note is that, while the Trustees' report, which is what this is based on, explains that the introduction of the prescription drug benefit increases beneficiaries' costs for covered services, it also reduces their costs for previously uncovered services by substantially more.

That is why I think you saw Rick Foster, our chief actuary, quoted in that USA Today story, saying that this was presenting a misleading picture. It is misleading to say that beneficiaries are worse off. That is not the case.

In fact, today, the biggest problem with Medicare for our beneficiaries, is there are so many services that it does not cover. Beneficiaries pay, on average, over $240 a month out of their own pockets for services that Medicare does not cover, things like preventive benefits, disease management benefits, and, of course, prescription drugs.

What the new benefit is doing is making those important uncovered services into covered services, so that beneficiaries may have co-pays, but they are going to be a lot better off than paying completely on their own for these services.

The new drug benefit is going to cover half the cost for a typical senior, and for low-income seniors, the ones who depend on their Social Security benefit check only, it is going to cover 95 percent of the costs. They are not going to face these kinds of out-of-pocket payments for uncovered services any more.

So if you add it all up, well over a quarter of the Social Security checks today have to go to services that Medicare does not cover. We are taking those and turning them into covered services. We are giving beneficiaries a lot of help with them, and that is why their out-of-pocket costs overall are going down.

Senator FRIST. Good. Thank you.

Senator Baucus?

Senator BAUCUS. Thank you, Senator Frist.

Dr. McClellan, I just, kind of in passing, wanted to again mention the problem we are having with the regulations with respect to employers keeping plans, and also the amount of subsidy given to employers, and so forth. I am not going to spend a lot of time on it, because I think others are going to raise it.

But the point is, under the law we said that the benefits employers provide have to be at least as generous as the Part D standard benefit. Now, the regulations do not really address that. That is, there is no definition of an actuarialy equivalent to a Part D benefit.

Rather, there are three options. The three options, it seems to me, are not quite relevant to the charge in the Congress to come up with a definition to make sure that the employers' benefit does meet, at least, the standard Part D benefit.

I am not going to spend time with you on this, but I would note that, and I think others have noted it. It is a big hole. It is a big gap. I have forgotten the dates here, but it is my understanding—and you can correct me—that a lot of these proposed regulations will become, I guess, final later on.

Many of the holes, the gaps that are not here, will supposedly be filled in later and then made final. That is, they are not going to be proposed regulations, they are going to be final regulations, which is a little bit concerning because a lot of the gaps and a lot of the holes covered very important issues.

The devil is in the details here. Some of us are concerned that there is a lot that is left undone that is going to be filled in without adequate public comment and participation, and so forth. I just warn you to be fair.

Someone said, who was very wise, do whatever it is, do it now, and do it right the first time. I would encourage you to do it right the first time.

The question I want to ask, though, is about another big gap, another big hole, as I mentioned in my statement, and that is the failure of the regulations to give much guidance on the size of the regions. The administration has said many times that there have to be large regions—maybe even a few, but large—so that PPOs could cover the rural parts of the country. As you know better than I, a lot of the plans say, oh, no, we want 50 different regions, State by State, or something like that.

Congress punted to you. You have now punted. So, could you give us some guidance as to how in the world you are going to decide the size of regions?

Dr. MCCLELLAN. Definitely, Senator. We are not going to punt on this decision. We are going to make all of the tough decisions needed to implement these regulations as effectively as possible.

What we have tried to do, is make sure we are getting public input into that process. We had a number of options that we presented on the possible alternative definitions of regions, ranging from a very small number of large multi-State regions, up to the full 50 State approach, that were discussed at a major conference in Chicago in the summer.

We have now gotten a lot of comments on those different proposals, on the discussion that we had. We are going to put those public comments out in summary form to make sure we are not missing something. The comments that we have received are pretty much as you outlined.

There are a lot of State-based health insurance plans that would like to continue business just as they are now. They are used to contracting just within the State. They have got good networks set up in the States. They are providing very good services in particular States, so would find it easiest to continue in that way.

On the other hand, we have heard from a number of large PPO plans, plans that provide PPOs to people all over this country today, including in more rural States, saying that they are supportive of multi-State regions. So it is not the case that we are hearing only in support for single State regions. I have heard from at least three, that support the multiple State approach.

Senator BAUCUS. You have got the point, namely, we want to make sure that plans are able to participate.

Dr. MCCLELLAN. That is right. And I think by getting this public comment——

Senator BAUCUS. And seniors will be able to enjoy the benefit of the plans. Now, frankly, I thought that we paid too much money to encourage PPOs to go these various places, but that is water under the bridge and this has already happened, or over the dam, whatever the phrase is.

But the point is, I am very concerned, and those of us in rural parts of the country are very concerned, that there is a lot of money, yet we have lots of other incentives going to these plans. MEDPAC, as you know, thinks it is way too much compared with fee-for-service payments.

We want to make sure that the rural areas are not discriminated against, that rural areas do not get the short end of the stick, with all these dollars going to urban areas where the plans are, but not to rural areas, partly because of a size definition, and so forth.

Dr. MCCLELLAN. Right.

Senator BAUCUS. Mr. Chairman, you have an awfully quick clock.

Senator FRIST. Well, since I am not chair of this committee and I do not have the——

Senator BAUCUS. No. The rule here has always been 5 minutes.

Senator FRIST. Take another minute.

Senator BAUCUS. I will stick with it. I will take advantage of your new chairmanship.

Senator FRIST. I appreciate it. Thank you, sir. I am easy.

Senator BAUCUS. The question is on dual eligibles. How are you going to make sure that they are treated fairly when they move into Medicare, the transition? We have a lot of questions here that are unanswered, namely, are they going to get, clearly, the same benefits? Then there are the QMBS and the SLMBS. Are they going to automatically get the same benefits, and so forth? It is very unclear.

Obviously, for people who participate in Medicaid today, seniors who are eligible for Medicaid, they get good benefits. There is a good appeals process. It is unclear whether these folks, the dual eligibles, who are now all under Medicare only are going to have the same appeal rights, the same benefits, and so forth.

Dr. MCCLELLAN. Well, as we made clear in the proposed regulations, all of the dual eligible Medicaid beneficiaries, people who are getting Medicaid drug coverage now, are going to be automatically enrolled in the new drug benefit, and they are going to have access to comprehensive coverage.

Senator BAUCUS. How about the others?

Dr. MCCLELLAN. Often it does not include limitations like on number of prescriptions, and so forth.

Senator BAUCUS. How about for QMBS and SLMBS?

Dr. MCCLELLAN. For QMBS and SLMBS, we are going to have an extensive outreach process. We have done what is called "deeming" them eligible already. We do want to make sure we get them enrolled, and we are going to be working very closely with the States and the Social Security Administration on this outreach effort.

For QMBS and SLMBS, we will be sending out letters in the coming months to notify them about it. We will be engaging in extensive outreach with local groups to make sure that they hear about the new benefits.

Senator BAUCUS. On the same subject, what about appeals rights? I mean, there are solid rights under Medicaid. It does not appear to be in these regulations.

Dr. MCCLELLAN. The law requires that beneficiaries get access to the prescription drugs they need, and we are going to make sure that happens. There is a full set of appeals oversights and drug benefit oversights that we are providing. It is not just the appeals, but our oversight of drug classification, of actual drugs included in the formularies, of tiering systems, of all of these different features of a drug benefit.

And we have put out some public guidance on that, and we have some discussions that are in the regulations. We are going to do a lot more. I agree with you completely that it is not just a matter

of making decisions on finalizing the regulations, but being very clear——

Senator BAUCUS. But making sure that they are treated at least as fairly as Medicaid in regard to that.

Dr. MCCLELLAN. That is right. Being very clear about the protections in place.

Senator BAUCUS. Yes. Thank you.

Senator FRIST. Good. Thank you.

Senator Breaux?

Senator BREAUX. I thank you, Leader. I appreciate Dr. McClellan's testimony.

I have got three points. First of all, I think Senator Frist went into this. The USA Today article says that the contribution of seniors under Social Security is going to be $35. That is a huge increase. But it does not tell the other half of the story.

The other half of the story, as I think you responded to, if someone is paying $200 a month for drugs now, they are going to pay $35 for an insurance plan which is going to cover that.

Dr. MCCLELLAN. That is right.

Senator BREAUX. I mean, so, yes, Social Security is going to be paying more. I mean, they are going to be paying more out of Social Security for the insurance, but the insurance is going to cover substantially more than the premium does. Seventy-five percent of that premium is going to be paid for by the Federal Government.

Dr. MCCLELLAN. That is right.

Senator BREAUX. And they will only be paying about 25 percent. That story is one-sided and does not clearly spell out what they are getting for the increase that they are going to be paying.

Dr. MCCLELLAN. That is right.

Senator BREAUX. They are paying $35 more, but they are going to have their drug coverage paid for. The ratio is, the government is going to pay 75 percent of the costs. So that, I think, cleared it up and I am glad you brought that up.

The other thing is, I have heard so much about—and you have addressed it in your statement—why in the world did Congress prohibit the Federal Government from negotiating the drug prices? That is unbelievable that you all did that.

Well, the fact is that almost every bill that has ever been introduced on this has had that same prohibition, whether it be a Democrat or a Republican introducing it.

In addition, our Federal Employees Health Benefit Plan that every one of us here, and all of our employees have, does not have the Federal Government negotiating our drug prices for our plans. It is privately negotiated and it is a competitive market.

In your testimony, you talk about how you are carrying this out in the regulations. So just tell the committee and everyone, why is that in your statement correct when you say, well, you are going to get a better deal if the government does not negotiate the price and you leave it to private negotiators? I mean, that is the theory behind it. That is what Congress did. You are implementing that plan. Do you truly believe that, and if so, why?

Dr. MCCLELLAN. We do, Senator. There are strong provisions in the bill to not only give power to negotiate for beneficiaries to get lower prices to negotiate on their behalf, but to help beneficiaries

get the best deal, get the best prices, plus the drugs that they want covered. The provisions include making sure that the prescription drug plans can go out and negotiate on behalf of their beneficiaries.

As you said, this is exactly how it is done in the Federal employees' plan. The reason that we think, and the Congressional Budget Office thinks, this is the best way to negotiate lower prices, is because there are very strong incentives to get those prices down.

We are going to make this prescription drug market more transparent than ever before. We started doing that with the drug card, where if you use a drug card you can get prices, the actual prices that you pay on your medicines at your neighborhood pharmacy so that you can easily find the best deal, much more easily than in the past when it was very hard for beneficiaries to find out just what a drug cost on their health insurance, or just what it would cost at their local pharmacy.

Senator BREAUX. Let me interrupt you on that. The State governments negotiate for drug prices under the Medicare program and the Federal Government negotiates on behalf of VA patients. Why is that not the approach that you would prefer?

Dr. MCCLELLAN. Well, the State governments mostly, now, negotiate prices by relying on private benefit managers, just as we are doing in this benefit. What they typically do, is put all of their Medicaid beneficiaries in just one plan with just one formulary. We have got enough power with all of our beneficiaries, and also enough diversity in our beneficiaries. They have quite different drug needs, quite different preferences about how they like to get their prescriptions and where they like to get their prescriptions, that we want to make sure they have got a drug benefit that not only negotiates lower drug prices just as those State plans do or just as the VA does, but then also make sure that it is for the drugs that they want.

So, we are not going to force them into a one-size-fits-all formulary, like, the VA formulary may not cover Lipitor or Celebrex or many other drugs that they use commonly. We are going to give them good information so they know exactly what they are paying for the drugs, and what is covered so they can get the best drug benefit that meets their needs.

Senator BREAUX. So your economists in the department, and the actuaries, and everyone else clearly tell you that the individual will get a better deal through the negotiation process we have and that you are writing the regulations for than if the government were to do it?

Dr. MCCLELLAN. That is right. In our analysis, in the independent analysis done by the Congressional Budget Office, the conclusion is, the prices are going to be the same, similar or better, than the prices that the government could negotiate and beneficiaries are going to have a better choice of drugs that is more responsive to their needs.

Senator BREAUX. All right. The law requires that at least two drugs be offered in every category—we are talking about choice—so that every senior will have a choice of which drug they want to get. You have, apparently successfully, made everybody mad in the proposed regulations, from the drug manufacturers to the pharmacy benefit managers.

The former people have said that what your proposal would do would be to "set back treatment for diabetes, asthma, heart disease, depression, migraine, epilepsy, gastrointestinal disorders," and that is not all, because apparently they feel that you do not have enough categories being proposed.

On the other hand, the Pharmaceutical Care Management Association representing the pharmacy benefit managers, said that "back door efforts by the drug manufacturers and their front groups to have 300 or more therapeutic classes of drugs covered in the formulary would be a blank check for the drug manufacturers and would eventually bankrupt Medicare."

So, you have got both sides thinking you have a disaster on your hands of what you are recommending. Apparently you all have about 146 categories. Is that about what we are talking about?

Dr. MCCLELLAN. You are talking about the proposal by the U.S. Pharmacopoeia, which is an independent group.

Senator BREAUX. Which you contracted out to set this up.

Dr. MCCLELLAN. Right. That is right. And they have a model system for drug classes. I think it is important to emphasize that drug classes are not everything that this drug benefit is about. We also care about what drugs are actually included. Do the drugs reflect modern medical practice? We also care about the actual prices that beneficiaries would pay.

If you include drugs in a class system and they are all covered at the third tier level, that is not really going to provide good access. We care about the other steps that the drug benefit might use to influence how people get their medicines, whether they have utilization review or things like that. We are going to be reviewing all of those factors. This is why we have this public comment process.

Senator BREAUX. You all have not made the recommendation on the number of categories yet. You are still looking at the data.

Dr. MCCLELLAN. That is right. And USP will make a recommendation for a model classification system, but that is not the only factor that determines whether or not a formulary is appropriate and whether it is providing access to the drugs that beneficiaries need at the lowest possible cost, and that is our goal.

We are going to have some comprehensive public guidance that we will have out for public comment first to make sure that we are taking account appropriately of all the factors that I mentioned that influence whether or not people can get the drugs they need at the best possible cost.

Senator BREAUX. So USP is going to be only one factor.

Dr. MCCLELLAN. USP is just one factor. That is right.

Senator FRIST. I think that is an important point. I think we will probably end up coming back to that whole concept. A lot of this is getting it on the table so we can come back and build on it.

I have one question, but I will wait.

Senator Smith?

Senator SMITH. Thank you, Senator Frist.

I want to also thank you for laying the predicate on this Part B premium issue. I, for one, was very disheartened when this was announced, that somehow President Bush was to get the blame for it, because I remember as a new Senator in 1997, as part of the Balanced Budget Agreement, we did this with President Clinton

and we did it as Republicans and Democrats alike. We laid the framework for Medicare's fiscal security.

Frankly, we probably overdid it. So what we did, Republicans and Democrats alike, with Senator Kerry included, we wanted to increase payments to physicians and plans because we did not want to have seniors have a low price, and nowhere to go to get service.

So, I just want to say, even to this limited C–SPAN audience, President Bush is not to blame for this. He is following the law, a law that we—I, Senator Kerry, and others—voted for. I think, in fairness, the American people ought to know that.

One of my concerns, Dr. McClellan, is on the issue of mental health. You have testified that USP has recently released its draft guidelines for listed categories and classes that will help drug plans develop their formularies.

You have done this, as required by statute. The guidelines will act as safe harbors, ensuring beneficiaries have appropriate and adequate access to necessary treatments while protecting drug plans from timely regulatory review by CMS.

It is my understanding that, while multiple classes were provided for anti-psychotic drugs, only one class was identified for a wide range of anti-depressants. Given the great degree of differences and side effects to these kinds of drugs, the wide variation in response rate from patient to patient and the overall effectiveness to each type of these drugs, I am somewhat troubled that USP has put all types of anti-depressants into one class. I further fear it will impact beneficiaries' access to the most effective and the most appropriate treatment.

So my question, Doctor, to you, is with respect to my fear that, with regard to treatments for persons with mental illness, USP has thus far failed in its undertaking to ensure that, in providing a safe harbor for persons who suffer mental illness, that they will get the right kind of drug that can be most helpful to them.

Can you elaborate on how protections will be given to ensure that beneficiaries with mental illnesses have access to as wide a range of drugs as possible when a new benefit is implemented in 2006?

Dr. MCCLELLAN. Absolutely, Senator Smith. I think the first part of the answer goes to my response to Senator Breaux earlier, which is that this USP model formulary is only one element that we are going to consider in our review, in our oversight of making sure that all of our beneficiaries have access to the drugs they need and that the drug benefit is adequate to prevent any discriminatory practices against beneficiaries that are suffering from any particular types of diseases.

We will have further guidance about coverage of drugs within any system of classification, about the tiering and the payments for those systems to make sure that they reflect current medical practice.

I am coming into this job from being in medical practice where I had a lot of patients who benefitted from some of these newer anti-depressants who did not respond to older medicines or did not respond as effectively, and those medicines are clearly a part of modern medical practice.

I have been reminded of that by our ongoing discussions and input from advocates for patients with mental illness, including the many patients in this country, the many Medicare beneficiaries with depression who are not being treated today because they do not know about the treatments available or they cannot afford the treatments available. So, absolutely, this is going to be the top priority in implementing the benefit effectively.

Senator SMITH. Well, I would appreciate your special attention to that issue, because I think sometimes mental health tends to get overlooked as we talk about physical health, and I think it has a real connection.

Dr. MCCLELLAN. I agree.

Senator SMITH. As you know, many members of this committee worked very hard to secure passage of the provision that extended Medicare coverage to a number of new oral anti-cancer and self-injectable drugs.

I was pleased when the final agreement on the Medicare Modernization Act provided $500 million for the next 2 years to extend coverage to these vital treatments in the absence of the comprehensive benefit.

However, it is my understanding that the guidelines for this temporary program are burdensome and the enrollment has, therefore, been extremely limited.

Given that enrollment for this program has not been very vigorous, as Congress has expected, or CMS as well, what are you doing to encourage enrollment, and is CMS reaching out to patients and provide groups to make changes to the program requirements, changing enrollment criteria or other things?

Dr. MCCLELLAN. Well, I think one of the biggest challenges with this drug demonstration program, which is now providing many thousands of dollars in help to beneficiaries who need potentially life-saving medicines, from multiple sclerosis or many forms of cancer, some types of lung disease, and other illnesses, is making sure that the beneficiaries who can most get help know about it.

This is a very narrow slice of our overall Medicare population. These are critical drugs, but they are only for beneficiaries that currently have coverage for drugs under Medicare Part B.

A lot of those patients are already in treatment and they are doing all right. They have to go into their doctor's office, and that is less convenient, but they are in treatment now so they are not going to suddenly switch. They are going to need to discuss that with their doctors. A lot of patients do not know about this new program yet. That is what we have found.

Fortunately, we have had a tremendous response from disease advocacy groups, including the American Cancer Society and the National Organization for Rare Disorders, and many other groups to help make sure beneficiaries who can get the most out of this program find out about it.

We are now seeing applications coming in at more than 1,000 a week. We are up to, I think, around 7,000 completed applications now, and many more phone calls. There was a notification about this in Parade magazine this past weekend that generated a lot more calls into the agency.

So, we need to make sure people know the facts, that by getting the same benefits that will be available in Part D in 2006, they can get drugs that they can take and administer themselves and save literally thousands of dollars. The application itself—and this is very important for people to know about—does not take very long to fill out.

When you call up our toll-free number—and you can get all the information if you call 1–800–MEDICARE—they will walk you through the whole application. It takes less than 20 minutes. To qualify for the full, comprehensive, low-income coverage, just a few more questions about your income and assets beyond that. So this does not take much time.

If you are struggling now in this country because you would like to get drugs that you can administer yourself rather than having to go to the doctor's office for Part B covered drugs, you should give us a call. There are slots available. It is not a hard process to sign up, and we can start giving you help right away with your costs.

Senator SMITH. So are you doing a rolling enrollment to ensure that all the $500 million is used?

Dr. MCCLELLAN. We are going to have another major enrollment period at the end of this month, so now is a good time to get the applications in. We will have rolling enrollments after that, to the extent slots remain available.

Senator SMITH. Thank you.

Senator FRIST. Thank you.

Senator Bingaman, then Senator Thomas.

Senator Bingaman?

Senator BINGAMAN. Thank you very much, Senator Frist.

Let me just clarify what I think the reality is here on this increase in the Medicare premium. There is a formula that has been in the law now for several years, essentially saying that the amount that people pay on their premium is based on the projected cost to Medicare. That is the general, shorthand version for what the law provides.

Dr. MCCLELLAN. Right.

Senator BINGAMAN. So the question is, why has the costs of Medicare projected to go up so much that we have a 17 percent increase in the premium? One of the reasons that the cost of Medicare is projected to go up so much and that the Part B premium is going up 17 percent, is because of these very large overpayments to HMOs that are built into the bill that we passed last year.

It was a prescription drug bill, but it calls for a substantial increase in over-payments to HMOs to entice people to get their health care through HMOs, and to entice HMOs to participate in this process.

So I guess my question is, if in fact you have got a significant portion of the 17 percent increase that is a result of the required overpayments, or the provided overpayments to HMOs, why should people, the 89 percent of seniors who have stayed in traditional Medicare, have to pay that full 17 percent, the portion of it which is going to subsidize the HMOs? They are not participating in HMOs.

In many cases, they do not have access to HMOs. They have no opportunity or they have chosen not to do it, whatever reason. Why

should they not be exempt from that part of the increase in the premium?

Dr. MCCLELLAN. Well, Senator, this is a premium that is set up by statute to cover 25 percent of the costs, as you said, and four-fifths of the increased benefit cost in Medicare Part B are going into the traditional Medicare program.

Only about a fifth is related to this change in the payments of the Medicare Advantage plans. The Medicare Advantage beneficiaries pay the same costs, even though a lot of the benefits in Part B are going to people in traditional Medicare.

In fact, the way that the formula is set up now, when there is an increase in traditional Medicare costs, which there was in this case because the payment reductions that were scheduled for the doctors were reversed, that causes a corresponding increase in payments for Medicare Advantage.

The traditional Medicare beneficiaries, for what they are paying in, they are getting better benefits and better access to physicians in Part B, better preventive benefits, and the like, and the Medicare Advantage beneficiaries are getting more than offsetting savings in their out-of-pocket costs.

We have done the analysis, and we saw this with the 2004 payment increases. They went into lowering out-of-pocket costs for premiums, for co-payments, for coverage of additional benefits like drug coverage for people in Medicare Advantage.

So, they are saving money on out-of-pocket costs from this payment increase, and the people in traditional Medicare are getting better benefits as well, and each of them are contributing just a portion of this overall cost.

Senator BINGAMAN. But each beneficiary makes the judgment, they want to be in traditional or they want to go into this new, whiz-bang program which has come up, these HMOs. If they choose to stay in the traditional Medicare, why should they have to pay that extra one-fifth? You say it is one-fifth of the 17 percent that is a result of the overpayments to HMOs. Why should they have to pay for that if they choose not to participate?

Dr. MCCLELLAN. It is one premium for all beneficiaries, and most of the increased premium costs are going into fee-for-service Medicare. So the Medicare Advantage beneficiaries who are paying these premiums, a lot of that money is going into fee-for-service Medicare.

Senator BINGAMAN. And that is the four-fifths.

Dr. MCCLELLAN. It is one program for everybody. That is the four-fifths. That is right.

Senator BINGAMAN. I am talking about the one-fifth. You said that one-fifth relates to HMO overpayments. Why should people who do not want to get their health care through HMOs, or do not have the opportunity to, why should they have to pay that extra one-fifth?

You could bring that 17 percent down one-fifth just by, at least for the people who are not participating in HMOs, by essentially making provision, or Congress could. Maybe Congress has to change the law. But it seems to me that it would be very fair for the 84 percent of the people in my State, 84 percent of the Medi-

care beneficiaries in my State who have chosen not to participate in HMOs.

Dr. MCCLELLAN. But then I think, to be completely fair, you would have to not make people in Medicare Advantage pay for all of those costs that are going into fee-for-service payments to physicians. Then I think it would definitely take a statutory change. What that means, is that beneficiaries would be paying less than a quarter of the costs.

So they are paying a quarter, they are getting out three times as much in benefits, on average, but it is something that all beneficiaries are in together and the costs go, in this case, mainly in the Medicare fee-for-service, but some go into Medicare Advantage, and they are all contributing to those costs.

Senator BINGAMAN. I will have to wait for my next round, Mr. Chairman.

Senator FRIST. All right. Thank you.

Senator Thomas?

Senator THOMAS. I wanted to talk a little bit about the distribution system in terms, particularly, of the pharmaceuticals. I come from a State that is low population and, therefore, for medical services we traditionally have not had the volume to really encourage insurance companies, and so on.

So in this matter of selecting the regions, are you going to try and set it up so that there will be enough volume in each of these regions to encourage bidding? It will be done by bidding. Is that correct?

Dr. MCCLELLAN. That is right. That is why we are going through this public comment process. We have actually gotten a lot of comments suggesting that the larger regions could be helpful in making sure that rural States like yours get good, broad access to the new benefits, the PPO benefits and the prescription drug benefit. That is why I am confident that we are going to find a way to get these benefits into those locations. We are just trying to figure out the exact best way to do that with a lot of public input.

Senator THOMAS. If Denver is included, however, as an example. But there are different rules for urban areas than rural areas. Could they exist within the same region, these differences?

Dr. MCCLELLAN. Well, one of the comments that we have gotten is that some plans would like us to allow for differences in benefits, differences in rules in one part of a region versus another.

The statute only gives us a limited amount of flexibility in accommodating that, though. It was written with an eye towards making sure that benefits got extended to all Medicare beneficiaries, regardless of where the live.

So, we are looking at comments about whether there are any adjustments that we should allow within regions, but I think our overall driving concern is, as the statute intended, that we make sure there are good benefits available to all Medicare beneficiaries, regardless of where they live.

Senator THOMAS. Good.

One of the things, of course, that people like and want, particularly in rural areas, are local pharmaceuticals, local drug stores, to go to. Now, as these bids take place, will these PPOs provide it for all participating drug stores or could they have some relationship

with a group of stores that are related to them in business and only use certain ones? How is that going to work?

Dr. MCCLELLAN. The PPOs and the drug plans are allowed to establish networks of pharmacies, but there are some strict rules that we will be enforcing to make sure that those pharmacy networks are very broad.

We have had some experience in this already with our drug card program. As you may know, there are a lot of cards that are participating very broadly in rural States and providing very broad access to pharmacies.

Many of these cards, many of these programs, include almost all of the nearly 60,000 pharmacies in the country, and we expect to see the same kind of thing with the drug benefit, with a number of options that are going to make sure that people have local access to the pharmacies they want to use, and we are going to give them good information to make sure they can find out how to continue to get drugs at the local pharmacy that they prefer.

Senator THOMAS. If I am a PPO, however, will I be able to give a better price to my choice of pharmacies as opposed to the others?

Dr. MCCLELLAN. Part of networking involves getting good volume arrangements. If you can get more people to go to certain providers, then they can lower their costs per person. They can provide volume discounts. That is true for pharmacies as well. But because of the broad access requirements, I think a lot of those network pharmacies are going to include local rural pharmacies. Again, that is what we are seeing right now with the drug card program.

Senator THOMAS. Well, I hope so, because rural areas would have trouble participating with the fair price.

Dr. MCCLELLAN. That is right.

Senator THOMAS. What about mail-order, again, trying to have local places to acquire drugs? Are they going to support and give better opportunities for mail or are you going to work through the local pharmacy?

Dr. MCCLELLAN. Mail-order options are going to be allowed, and in some cases they can provide significantly lower prices for beneficiaries who do not mind getting their drugs that way, who do not mind not having face-to-face interactions and back and forth with their pharmacist.

But what we have seen, and both in my talking to beneficiaries around the country and all the work that we have done for this drug benefit, is that most beneficiaries, most Medicare beneficiaries, prefer to get their drugs through local pharmacies through face-to-face contacts.

Again, that is why we are going to have these very broad access requirements for the pharmacies. We have been working very closely with pharmacy groups to make sure that we set up this drug benefit in a way that will make it possible for people to get big savings at their local pharmacies.

Senator THOMAS. I hope so. I think there is a movement towards involving local pharmacists more in the kinds of things you do, and we have been encouraging, in fact, to get people to go to their pharmacists to talk about these cards, and so on. So, I hope we can keep those folks in the process.

Dr. MCCLELLAN. We intend to.

Senator THOMAS. Thank you.

Senator FRIST. Good.

Next, we have Senator Nickles, followed by Senator Graham.

Senator NICKLES. Mr. Chairman, thank you very much. Dr. McClellan, thank you. It is kind of interesting, participating in this hearing. It brings me back to the many months that we spent putting together this bill. It is kind of interesting to hear your explanation. It will kind of refurbish our memories as well as to some of the things that we did.

Let me just ask a couple of questions. There was a lot of negative press on the percentage increase in the Part B premium, 17 percent, and people were shocked, how could this be. We started looking at it. Oh, well, it was because we made some actions to increase physician payments, outpatient hospitals. We had additional services, and so on.

I would mention that there has been some discussion by some members of Congress that, well, we should limit the increase to whatever the cost of living increase is for Social Security. If that was done, say, for this year, what would the increase have to be for next year on Part B?

Senator, according to our actuaries, in addition to the budget costs of doing that this year, a 1-year change in the law that was not continued would cause an increase of almost 20 percent in premiums next year, which is much higher than what we are expecting.

Senator NICKLES. I appreciate that. I think it would be a mistake to do that, and I expect that I would oppose it very strongly. I think it would jeopardize the financial basis that we have with Medicare, and it already has some big challenges, actually much bigger than even Social Security.

Let me ask you a different question. How is the sign-up going for the drug cards? How many people have actually signed up? What percentage of eligible people have signed up?

Dr. MCCLELLAN. We, right now, have close to 4.4 million people enrolled in the drug card program. Even during the slower month of August, we were getting 10,000 people a day. Recently, as there has been more attention to the fact that there are real discounts available that people can save, and it is not hard to sign up, we have seen a pick-up in the phone calls coming in.

I am especially interested in the fact that there is now a broad group of nonpartisan organizations coming together through the Access to Benefits Coalition to help enroll people in low-income assistance.

So the drug card is providing significant discounts to all Medicare beneficiaries who do not have good coverage now and who sign up for the card, but for low-income beneficiaries they also get $600 this year, $600 next year, and now wrap-around discounts from a large number of drug manufacturers, including on 6 out of the top 10 drugs, very commonly used drugs like Lipitor, for example, that offer thousands of dollars in more help.

We have already got well over a million low-income beneficiaries signed up for this program and we are going to be working with some new ideas to get many more enrolled as well.

If you take a step back and look at the big picture, and we tried to look carefully at this when we were setting up this new program, about how had other new Federal health benefit programs gotten off the ground, and how do you overcome the barriers, it was very clear that we needed to do a lot of local outreach, we needed a lot of partnerships in health, in getting the true facts out about the program, and we are trying our best to do that.

But it is also clear that it takes a little bit of time. For exmaple, the Children's Health Insurance Program, at the end of its first year, had a little over a million people signed up, around 50 percent or so of the targeted enrollment. We are, right now, approaching 60 percent of the target enrollment in this program after just a little bit over 3 months.

So I am hopeful that, by continuing this broad support for outreach, to get the facts out about the program, to let people know they do not need to go on the Internet, they just call 1–800–MEDICARE, they can find out exactly how much they can start saving right away. They can sign up for the card in less than a half hour. I hope that many people now who are not yet taking advantage of these important savings will soon start to do so.

Senator NICKLES. The people who would be the primary beneficiaries of this would be people who do not have access to drug coverage now as seniors?

Dr. MCCLELLAN. That is right. The people with drug coverage now through an employer or other source are going to get help in 2006 with our new employer subsidies and with our new help to States, but this is a short-term program intended for people who are paying on their own for a lot of their drug costs, and in too many cases are paying the highest prices in the world.

They do not need to do that any more, especially low-income beneficiaries. They do not need to be choosing any more between drugs and other basic necessities, or skipping doses, or not refilling their prescriptions, because there is thousands of dollars worth of help available right now with just a phone call to 1–800–MEDICARE.

Senator NICKLES. So if someone was not receiving assistance from their employer, by joining this, signing up for the card—and most of the cards, in this case, would cost $20 or $25, and for low-income people, I think that is waived, is it not?

Dr. MCCLELLAN. It is free. Yes.

Senator NICKLES. And the low-income people would be eligible for the $600, and possibly more.

Dr. MCCLELLAN. And more.

Senator NICKLES. And in addition to that, all people who would sign up would be eligible for the discounts. The discounts are averaging about what percent?

Dr. MCCLELLAN. Well, independent studies, not ours, are showing 20 percent or more for brand-name drugs at local pharmacies, and for generic drugs, 50 or 60 percent or more. Also, we will give you information on how to find cheaper versions of your drug. There are generic drugs available and so forth that can offer much more savings on top of that. A new study by the Lewin Group, out just a few weeks ago, found that for this program, for just 18

months, people can save, on average, over $1,200 in getting their drug costs down.

Senator NICKLES. Thank you, Doctor. I appreciate the good work that you and your staff are doing.

Dr. MCCLELLAN. Thank you.

Senator FRIST. Thank you.

Senator Graham?

Senator GRAHAM. Thank you, Senator Frist.

I would like to use the first four minutes to ask some questions, and then the last to make a comment.

Dr. McClellan, you said that today the average Medicare beneficiary is spending $240 a month above their Medicare benefits on health care.

Dr. MCCLELLAN. That is on uncovered services. They are spending more than that out of pocket because of the gaps in Medicare.

Senator GRAHAM. Could you outline how the new Medicare reform bill will reduce, and the quantity of the reduction of that $240?

Dr. MCCLELLAN. Absolutely. The $240 in uncovered services, until this law, included preventive benefits, like for cancer, heart disease, diabetes.

Senator GRAHAM. What is your estimate, starting with your list, of the dollar savings that will be accrued as a result of that?

Dr. MCCLELLAN. I do not have a specific dollar figure because it varies for different types of beneficiaries. For the low-income beneficiaries, they are going to get 95 percent of their drug costs covered, on average. That is a benefit worth about $3,500, on average.

For typical Medicare beneficiaries, people who do not qualify for the low-income assistance, a typical beneficiary will get half of their costs covered. So, that is a savings of about $1,270, about half of the cost of drugs today. So, those are substantial amounts of savings. We have these numbers in our proposed regulation for public comment, too.

Senator GRAHAM. Could you submit for the record your estimate of how components of the Medicare reform bill, by classes of beneficiaries, will affect their costs of uncovered services?

Dr. MCCLELLAN. We will do our best to work with your staff on that, to make sure we get the numbers exactly right. But we would like to do that. There are some real reductions in out-of-pocket costs because many of these services, like drugs, and prevention, and disease management, are moving from uncovered to covered status, so beneficiaries are going to get a lot of help that they do not get now.

Senator GRAHAM. It would be helpful to quantify that statement.

Dr. MCCLELLAN. Yes.

[The information appears in the appendix.]

Senator GRAHAM. An issue that I have raised before, both in committee hearings and by correspondence, has been the coverage through the PET program of medical evaluation for multiple myeloma cancer. In a letter that you sent on the 16th of August, you state that "we will announce shortly whether we will accept a reconsideration of our current decision." Could you give a date by which time you think that might occur?

Dr. MCCLELLAN. Yes. As a result of your interest in this, and also because it just is an important new technology, Positron Emission Tomography is now used in imaging for a number of diseases, including possible benefits in multiple myeloma, we have been taking a close look at this.

We convened an expert panel, with help from the National Institute on Aging and the Alzheimer's Association, for some other PET applications, and we are looking into this, too.

I cannot give you an exact date, but we expect to have a major announcement related to PET coverage in the coming days, like within the next week or so, and we will be working promptly on this aspect of PET coverage as part of that overall effort.

One of the other things that I announced earlier this year, is that we are going to be funding the clinical cost of care in studies related to PET use, so that where there are important, unanswered questions—and that may be true in this myeloma case—we can get them answered.

Senator GRAHAM. Would the answer to the question be, by the end of September you would have an announcement?

Dr. MCCLELLAN. Certainly I will go back and try to make that happen, Senator. I know how important this is to you.

Senator GRAHAM. Next, another subject that we discussed is the issue of negotiation for pharmaceutical costs in a hospital setting. Of course, Medicare has covered drugs in a hospital setting almost since the beginning of the program, if not from the beginning of the program.

It would seem to me that, given the shaky status of the Part A trust fund, that if we could reduce a hospital cost by a program which would make pharmaceuticals more accessible and affordable, that would be a benefit to the Part A program.

What is the status of CMS negotiating on behalf of hospitals?

Dr. MCCLELLAN. Well, we are, as you know, taking steps for Part B drugs that are used in hospital outpatient departments to get the prices down and more accurate, and that is a source of savings this year in Part B.

Senator GRAHAM. I am talking, in the Part A program.

Dr. MCCLELLAN. In Part A, hospitals, right now, negotiate through purchasing groups to get lower prices on their drugs, and we can look into that more closely. I think many of them are getting pretty good prices now, but we would certainly be interested in steps to help get those drug prices down for the most effective negotiations means possible.

Senator GRAHAM. I would like you to evaluate what those savings by individual hospital negotiations are in comparison to what the VA secures by the mass negotiation that it does for all of its 109 hospitals.

Dr. MCCLELLAN. We will look into that. As you know, the VA is a little bit different in that it owns the hospitals. In this country, most of the hospitals, as you well know, are private. They are nonprofit, mainly. They make their own decisions.

They are not subject to the direct government determination of exactly which drugs they provide their patients and how they provide services, in the same way that the VA oversees care in the VA system. So, that is an important difference. But I do want to make

sure we are helping hospitals as much as possible get their costs down.

Senator GRAHAM. This seems to me to be an area in which hospitals, the taxpayers, and the beneficiaries all have a common interest, is in restraining the cost of pharmaceuticals in a hospital setting, and that your agency is the centerpiece in making that happen.

Senator FRIST. Was that part of your statement?

Senator GRAHAM. I have used my time. I will hold for the next round.

Senator FRIST. All right. Or if you would like to go ahead and make it. We will turn to Senator Lincoln, then we will come back through quickly. I know we have another panel following this, but I want to make sure everybody does have the opportunity to question and interact. We will go ahead and go through a second round, and then we will go to our second panel.

Senator Lincoln?

Senator LINCOLN. Thank you, Senator Frist.

Welcome, Dr. McClellan.

Dr. MCCLELLAN. It is good to see you again.

Senator LINCOLN. I am not trying to be intimidating, because you all did beat us on Saturday.

Dr. MCCLELLAN. It was a close game.

Senator LINCOLN. It was.

I still remain very concerned about the drug discount card. The last time we talked in June, you had said that CMS was working with the States to basically determine how they could best automatically enroll seniors in the Medicare savings program in the drug card.

I am convinced it is the best way to ensure that these seniors get that $600 a year, and you have got three and a half months left. I am really concerned that time is running out. So maybe you could update me on the process, or whatever progress you have made in those automatic enrollments.

Dr. MCCLELLAN. I would be glad to give you an update, and this is for Senator Bingaman, too, because I know he feels very strongly about us getting as many low-income people into the tremendous help available through this program as possible.

When we talked last, we were exploring whether States could use the same kind of approach as they use for enrolling their prescription drug assistance plan beneficiaries. These are people who are in limited State drug benefits now which would qualify for the help.

Senator LINCOLN. But you already automatically enrolled those. We do not have that.

Dr. MCCLELLAN. That is right. We automatically enrolled them through a process with State help, where the State acted as authorized representatives for these beneficiaries.

That approach, it turns out, is not going to work here because the States generally do not have that authorized representative authority, and they have not passed, and do not seem willing to pass, legislation to change that. So, we are working on a different approach.

We have been talking not only with your staffs, but with a lot of these organizations that are very interested as well in getting help to low-income groups, like the National Council on Aging, AARP, and many other organizations that make up the Access to Benefits Coalition, and we are making a lot of progress in coming up with a new way to enroll these individuals. We have reviewed our authority.

We are going now on an approach that does not involve relying on State authorities at all, and we are going to have more to say about this very soon. I will make sure that your staff is among the first to know. We have made a lot of progress on this, and I am optimistic that we are going to be able to boost the enrollment of low-income beneficiaries into this program.

Senator LINCOLN. Do you know how many low income you have enrolled? What is the percentage?

Dr. MCCLELLAN. Yes. We have got over 1.1 million low-income beneficiaries enrolled now. That is a significant part. It is not as many as I would like.

Senator LINCOLN. Do you know the percentage?

Dr. MCCLELLAN. Well, we were expecting about close to 4 million low-income beneficiaries to enroll in this program by the time it concludes, and we have seen a pick-up in this enrollment recently with help from the Access to Benefits Coalition.

Senator LINCOLN. Is that 4 million your goal?

Dr. MCCLELLAN. I am sorry. I have got a corrected number. There are 1.8 million enrolled now.

Senator LINCOLN. And 4 million is your goal?

Dr. MCCLELLAN. That is what we expected would be the enrollment by the end of the program.

Senator LINCOLN. And do you know what percentage of the low income that is?

Dr. MCCLELLAN. I think it is most of the low-income beneficiaries who do not have drug coverage now through Medicaid or another source.

Senator LINCOLN. That would qualify under the MSP program.

Dr. MCCLELLAN. Yes. Many of them would qualify under MSP. As you know, MSP is another program, one of the Medicare savings programs, where the enrollment is not as high as we would like. A lot of the outreach that we are doing now with these outside groups and with Medicare directly is also informing people about the Medicare savings program, which can pay for their premiums and provides other important benefits as well.

Senator LINCOLN. Right. Well, I mean, I guess, as you are doing this in a dual situation, you are taking certain steps to ensure that the low-income subsidy applicants for the drug card are also being screened for the MSP.

Dr. MCCLELLAN. That is right. This is going to be an even bigger issue as we prepare for the full drug benefit in 2006. As you know, under the law, the law includes provisions to get States to help us enroll people who are not eligible now, and we are also getting new help from the Social Security Administration doing enrollment in the drug benefit.

Senator LINCOLN. But just tell me, just so I understand, why is it that you feel like you cannot automatically enroll these people?

I mean, you have got their data. You know who they are. You know who these people are on these MSPs. It is in your data bank. You know that they have already qualified, because they qualified for the MSP program.

Dr. MCCLELLAN. The way the law works, is this is a voluntary benefit. It was very important to members of Congress in both parties that the prescription drug coverage be voluntary.

Senator LINCOLN. So you cannot just sign them up. You have got a rolling enrollment that they can change whatever program they are in, but to go ahead and get them that $600, which they are going to lose in the next 3 months.

Dr. MCCLELLAN. We do not want them to lose it. It is valuable help that people who are struggling with drug costs need right now. So, as I am saying, there is more that we can do to make it even easier for people to get those benefits.

Senator LINCOLN. But you are just saying that, because it is supposedly a voluntary program, you cannot go ahead and automatically enroll them.

Dr. MCCLELLAN. Yes. It is a voluntary program.

Senator LINCOLN. But you could automatically enroll the managed care folks and the State groups because you went through their managed care and you went through their State. Is that what you did?

Dr. MCCLELLAN. The people who have signed up for Medicare Advantage programs have, often, drug benefits and drug help included in that. So, there is already a statutory structure when they voluntarily choose to enroll in Medicare Advantage, and in most cases they do get help with prescription drugs already and the drug card is added to that.

For the State programs, the State has acted as the authorized representative of the beneficiary in making the decision on the beneficiary's behalf. So what we are trying to do here, is go through a different approach without the State to make it as easy as possible for the low-income beneficiaries to start getting help.

Senator LINCOLN. Do you know where the auto enrollees are located? Do you have an indication of that?

Dr. MCCLELLAN. Well, they are located all over this country. There are a lot of them in your home State of Arkansas.

Senator LINCOLN. Automatic enrollees? We do not have a State plan and we do not have managed care.

Dr. MCCLELLAN. I am sorry. Low-income. Sorry. I did not mean to say automatic enrollees. Sorry. The automatic enrollees are in States that have this authorized representative status, States like New Jersey, Pennsylvania, Connecticut, Maine, Michigan, New York, North Carolina.

Senator LINCOLN. Not the ones with the bigger percentage of low income proportionately, probably. Right?

Dr. MCCLELLAN. Well, some of them, States like North Carolina, do have a large share of low-income beneficiaries. But we are very interested in working with you on getting beneficiaries in other States like Arkansas, where we do not have the straightforward mechanism. The State does not have authorized representative status there, so we are trying to find this other way to get the most help to those beneficiaries.

Senator LINCOLN. And, last, can you tell me how many Arkansans are enrolled in the drug card today? Do you all have that information for us?

Dr. MCCLELLAN. I do not think I have State-specific numbers, no.

Senator LINCOLN. So you do not have any State-by-State enrollment?

Dr. MCCLELLAN. No, I do not. We are going to try and make that available as soon as we can.

Senator LINCOLN. All right. That would be great.

Thank you, Senator Frist.

Senator FRIST. Thank you, Senator Lincoln.

We do have a second panel. Do we want to go through and have another round of questions? All right. Let me then kick off really a follow-up from where my questioning was before.

Let me preface my question with an appreciation of what we have done in this Medicare Modernization Act in terms of, from a physician or doctor/patient relationship, the sort of very positive things that we have done with prevention and chronic disease management, and the rich complexity of it, but the richness of it comes out in hearings like this and will really come alive once this is implemented.

My questioning before was about the 17 percent increase in the premiums which has been so much in the press. That comes back to physician services. Then you say, well, what are driving those physician service costs?

It is the expenses of a physician of operating their practice, in large part. One of those major drivers that we all know, and a lot of people are beginning to talk about today, is the skyrocketing medical liability costs.

As a physician, people come up to me all the time, my colleagues, and basically tell me today—and it is different than even 5 years ago or 10 years ago where costs were going up—that now they are becoming unbearable.

With 20 crisis States, however that is defined, if you go to New York or Pennsylvania or Ohio, physicians are leaving the practice. That is not an overstatement. Literally, they are stopping delivering babies because of $100,000 to $200,000 premiums that they are having to pay. It comes back to frivolous lawsuits. Every time we try to take it to the floor, it breaks down. At some point, we have to address it on the floor and it is going to take bipartisan work, and I recognize that.

But we have, with Dr. McClellan, before your current position, you have been an academic. You have practiced medicine. You have written extensively on defensive medicine.

And since we are talking about premium increases from our colleagues, and that is the discussion today, could you comment, based on your sort of body of knowledge, your experience now, but also what you have studied, this impact of skyrocketing medical costs in terms of access, what it is doing in terms of defensive medicine, the waste that comes from people like you or me ordering tests to protect ourselves from a frivolous lawsuit that we know is out there?

Dr. MCCLELLAN. Well, there is a lot of evidence, both that doctors often have to practice defensive medicine because of the liabil-

ity pressures that they are facing, that that can add to medical costs through extra tests, extra services, and the like, and also that reforms in medical liability laws significantly affect those costs and we need to get them down without compromising quality of care.

In this era of rising health care costs, we need to be looking at every way possible to reduce costs, but without compromising quality, not by cutting benefits, not by shifting costs to someone else, but just by delivering our care in a better way.

According to the Congressional Budget Office, Medicare could get $11 billion in savings in reduced liability premiums that we pay out through medical liability reform law, and that is not even counting the potential savings from affecting defensive medicine, getting more effective medical practice into play. So, there is a lot of opportunity for savings there.

What I am most concerned about, again, coming from medical practice, is that I am hearing from doctors in a lot of places in the country, OBGYNs, emergency medicine specialists, trauma surgeons, and the like, that they are just leaving practice. So, in a number of areas in the country there is a significant access problem that affects our program, so it affects us on the cost side. We had some of the increase in costs in the Medicare payments to doctors in 2004 that was due to medical liability payment increases. It affects us, most importantly, on the quality of care side where beneficiaries are not getting errors avoided, they are not getting access to the services they need because medical liability gets in the way.

And I know this is going to take legislation to fix, but as you know, the Senate did pass a bill earlier this year to provide some liability protections to allow doctors and health professionals to talk about ways to avoid medical error, something that they are afraid to do now because it could get discovered in court.

It will not directly reduce people's ability to sue, but it will make it easier for doctors to work together to prevent errors and the complications in the first place. Even that step could have a big impact on costs and quality of care in Medicare.

Senator FRIST. I think this is the patient safety legislation which the Senate has acted on, and which we encourage the House to act on and the President to sign.

I just think this increase in premiums should force us to say, what is driving costs up for physicians? A $400,000 tax—I do not know what you would call it—or premium for a neurosurgeon to have the privilege to be able to take call at night in case we get into an accident, that $400,000 is given to an individual.

How can society expect an individual who has dedicated his or her life to taking care of people to say, for that privilege, I will pay $400,000? You just cannot afford it. Nobody could afford it.

Ultimately, it has to get factored down to somewhere, and it gets factored down to your practice expense, and the practice expense ends up getting factored into things like the 17 percent, but much broader than that, every premium that you pay has this additional tax.

The statement that Dr. McClellan made that I think we all need to do a better job of articulating, is we want to make sure everybody is taken care of who has been wrongly hurt, appropriately,

make sure physicians are punished, thrown out if they do something wrong, and we need to address those errors in there. But we have to get rid of the frivolous lawsuits that drive the premiums that we all pay, including this 17 percent increase that we are seeing today.

Mr. Baucus?

Senator BAUCUS. Thank you, Mr. Chairman.

Dr. McClellan, this is a hearing on implementation. It is supposed to be, anyway, of the regulations of the Medicare bill. I appreciate the comments that have been made today about people who like or do not like the Medicare bill, but if we are going to get confidence in government, it seems to me that we are going to have to make sure that this committee performs its oversight roles as well as we possibly can, and help ensure that the regulations are the right regulations so that the Medicare law that I voted for, and others voted for, is implemented fairly and correctly.

So to that end, and because I do not have much time, I have several questions. I will just state them so that you know what some of my concerns are, and if there is time left, you can answer. I doubt that there will be.

First, I am a little concerned about the process we are seeking for the exceptions to formularies. I understand that, under the proposed rule, there is no uniform standard for plans regarding what that process would be to seeking an exception to a formulary, and the proposed rule basically just allows plans to set up their own process, their own rules for allowing people, seniors, to seek exceptions of the formularies.

I, frankly, do not think that is right. I think we have a uniform standard in the Medicare+Choice, but the proposed rule does not seem to be as tight here.

Second, I understand that rules allow private prescription drug plans to exclude nursing homes or Indian Health Service pharmacies from the networks. I wonder if that is really fair. A lot of us come from States where there is a sizeable Indian population, and it just seems to me that they should not be dealt out.

In addition, I am concerned that CMS has allowed contributions from private entities to count toward out-of-pocket limits, but not with respect to IHS, VA, or other programs such as State pharmacy plans. It just seems to me, if private contributions are allowed in some areas, they ought to be allowed across the board.

Next, I am very concerned about the lack of enthusiasm for the drug discount card, and I wonder what CMS has learned from all that. I, frankly, believe that there are too many choices in the drug discount card. I think that too many choices, too many options, can result in paralysis, not liberation.

There comes a point where there are just so many choices, people are overwhelmed. I read an article months ago in the New York Times, some op-ed piece, that made the point very clearly. Psychologists have documented this. When you have too many choices, people do not choose. When you have fewer choices, they begin to choose.

Next, I am concerned with criteria with respect to the fall-back plans. I very much appreciate, however, the administration's strong

adherence to the fall-back plans. So, that is a very important part of legislation.

However, it seems to me, under the rules, one of the criteria for selecting the fall-back plan would be the fall-back plan's ability to negotiate discounts. That does not apply to PDPs, for example, applying to participate. It seems to me, if you are going to have discounts, if the criterion for fall-back is discounts, it ought to apply also to PDPs.

Next, and finally, I am still concerned about the failure of CMS to enact a budget-neutral risk adjustment. By budget neutral, I mean risk adjustment for all Medicare beneficiaries, not just plan HMOs' and PPOs' beneficiaries, but also fee-for-service beneficiaries.

As you know, MEDPAC strongly suggested a budget-neutral risk adjustment, and CMS has not implemented that. It seems to me it is only fair, so particular plans do not cherry-pick, so it is fair to everybody and do not get over-paid, as some think that they are.

Those are my questions. Those are some points I have. You have about 30 seconds.

Dr. MCCLELLAN. If I might, I will take just a few seconds. Those are all good questions. I would like to start by thanking your staff for working so closely and constructively with us on raising concerns and making sure that we address all of the key issues that come up in this law. You put a lot of effort into getting this done, and we are going to put a lot of effort into getting it implemented correctly.

With respect to your question about the exceptions process for formularies, we are going to be setting standards for how the plans oversee their internal exceptions process, and there is an appeal beyond that externally. We will be setting specific standards for that. We are getting public comment on that right now.

On Indian Health Service and Indian country participation in the drug benefit, our questions at this stage are just about the ways to do this as effectively as possible.

We have had a lot of comments and discussions with leaders from Indian country, with the IHS, about how to do that, and that is going to be reflected when we make decisions in the final regulation.

We absolutely intend for American Indians who are in Indian country to get the full benefits of this new legislation. We are bringing the drug card there as well right now.

Senator BAUCUS. Hear, hear.

Dr. MCCLELLAN. On your question about choices in the drug card program, that is something that we also want to make sure we address. One of the comments that we got back early on was that people did not want to be overwhelmed with a lot of choices.

So when you call us up now at 1–800–MEDICARE, we ask you just a few questions about where you live, your drugs—you can get information off your pill bottles—and what pharmacy you like to go to, and any other factors that you want to use in choosing a card, if you have heard about one that you like, and then we will just give you information on as many cards as you want to hear about. So, it can be a program for you.

Even if there are 40 cards available for everyone, this program for you can have just one, two, or three cards, however many you want to take the time and trouble to look at.

The point is, people should look into this program because the discounts are really there. They have been shown in many independent studies now.

I am pleased that we have got millions of people signed up, that we are running ahead of enrollment rates in previous new Federal programs. But there clearly are more people that can get help, and we are going to keep taking steps to make it as simple as possible for them to enroll.

You asked about fall-back plans negotiating discounts. That is something that we are going to be overseeing carefully. I do not think we are going to need to get to fall-back plans. I am encouraged by what I have heard from potential participants in all regions of the country.

We may need to limit risk in other ways, but we are going to make the benefit available. One of the strengths of the way that the prescription drug benefit is being available, is that it builds in the strongest possible incentives to get drug prices down.

When the government is just paying an unlimited amount into a benefit, there is not a strong incentive to lower prices. When beneficiaries can choose a plan that gets them the best prices on their drugs and it gets them the coverage they want, there is a strong incentive.

But we will be making sure that we are implementing the drug benefit in a way to get the lowest possible drug prices negotiated for beneficiaries, whether they are getting it through a regular drug benefit or if we need to go there through a fall-back plan.

On risk adjustment for the Medicare Advantage plans, you have got a lot of good issues here. Most of the payments that are going into Medicare Advantage this year, because we are increasing our application of risk adjustment, is going to beneficiaries with chronic illnesses.

And as I said, these plans are enabling many beneficiaries to lower their out-of-pocket costs substantially, and that is particularly true for beneficiaries with chronic illnesses.

And as we keep moving forward, we are going to be keeping on increasing the amount of payments that are risk adjusted, so most of the new funding going into Medicare Advantage is going straight to better benefits for people with chronic illnesses and high out-of-pocket costs otherwise. We need to give those beneficiaries that help. We need to get these plans into Montana, and that is what we intend to do with the PPO program in 2006.

Senator BAUCUS. I appreciate that. I want to work with you to make sure this law is implemented fairly, and these are issues that I am going to be watching.

Dr. MCCLELLAN. We will be working closely with you and your staff on this.

Senator BAUCUS. Thank you. I think that is right.

Senator FRIST. Senator Breaux?

Senator BREAUX. Thank you very much.

Two questions. First, if a drug is not covered in a plan, the beneficiary has the right to appeal that drug not being covered.

Dr. MCCLELLAN. That is correct.

Senator BREAUX. It seems to me that the proposed regulations are fairly flexible on how that appeals process is going to work. As I understand it, it would allow each one of the plans to essentially design an appeals process.

My concern, is a number of things. You could have a different appeals process depending on which plan you are in, so you could have a whole number of different appeals processes that may be different depending on which plan you are in.

I am concerned that plans may require a great deal of information from a senior on the merits and efficiency of the drugs that they are saying should be covered and are not covered, which they are not going to be able to handle.

It seems to me that, under the Medicaid appeals process when a drug is not on a formulary, it works fairly quickly. So, I am really concerned that the process is light on details as far as the appeals process, and how is CMS going to be oversee it if each plan can have their own appeals process? It seems like you would have one universal appeals process that would say very clearly what has to be provided.

Can you comment on that?

Dr. MCCLELLAN. Well, yes. I mean, the process is not going to be entirely up to the plans. Just as we do for appeals process in the Medicare Advantage program now, we are going to have standards and we are going to have oversight to make sure that the plans come up with an appeals or an exceptions process that is based on good medical evidence and medical practice and that is minimally burdensome for the doctors, for the pharmacists, and especially for the beneficiaries involved.

And you mentioned there are some good models of this in some—not all, but some—State Medicaid programs where they pretty much automated it, so the beneficiaries are not expected to go pull the medical journals and come up with a very comprehensive review of the evidence in their particular case, but rather there is an automated process that uses information technology to check off a few specific issues related to prescription drugs.

So, some Medicaid programs, you would have prior authorization and exceptions processes for Cox 2 inhibitors which can reduce inflammation and may have some benefits in some patients, but in other patients a less expensive generic drug may work just as well.

Well, in some Medicaid programs there are now computerized checklists that the beneficiary can go through very quickly to help decide if this is something that they really need or if the other medicine would work just as well. That is the kind of thing that we are looking at right now to try to make this exceptions process and the appeals process work efficiently.

Senator BREAUX. I would just caution you to make sure we have some standards out there so we do not have a different appeals process for every single plan, and make it so complicated that it is not going to function. I think it is important.

I mean, there is a reason for formularies. I mean, there is a reason for them. I do not imply that anybody who wants a different drug because they saw a new ad ought to be able to get it, but

there ought to be a process that is fairly standard, to the extent that we can.

A final point. One of the more important things that I think we did in the Medicare bill was to provide for a baseline physical for new entrants into the program. I would have made them mandatory, had I had a chance to do that.

You do not buy health insurance in this country without having a physical exam so that people know what type of customer they are getting. Only Medicare says we will take you no matter what your condition is, and we will not even ask you what it is.

So, I think that the baseline physical is good for everybody. It is good for helping to reduce costs, for catching early illnesses that are preventable or delayable. I would like to make it as mandatory as we possibly can, but the law does not require that.

So the next step is to make sure that everybody knows that it is available and encourage them to partake of something that their government is going to pay for to give them a baseline physical to tell them if they have diabetes or it is getting ready to occur, or if they have cardiovascular disease which is getting ready to occur so we can start doing more preventative medicine early on because we know what type of problems they have.

So could you comment on how that section of the regulations is going to work?

Dr. MCCLELLAN. Well, I think this is an absolutely critical section of the new Medicare benefits. With the passage of the Medicare Modernization Act, Medicare now provides coverage for most—for just about all, in fact—of the preventive treatments that are recommended now for America's seniors and people with disabilities, screening for cancer, screening for heart disease, screening for diabetes, and especially this new physical exam that you mentioned.

We have the opportunity to turn Medicare into a prevention-oriented program for the first time ever. Up until now, virtually all of the money spent in the Medicare program has gone into dealing with the costly complications of illnesses after they occur, probably 95 percent of our spending.

We are really going to try to change that with the new preventive benefits, and also with the new disease management and chronic care improvement services so that we can both get healthier beneficiaries and lower our costs by avoiding all these costly complications.

This fall, we will be launching a major outreach effort to beneficiaries and to physicians to let them know that Medicare has a new orientation to prevention, to let them know that there are many benefits out there that they are not taking advantage of.

Only about half of our beneficiaries that are eligible for colon cancer screening are taking full advantage of that benefit, with the result that many are developing cancers that could have been treated if they had just gotten the screening, but that now lead to added costs for dealing with metastatic cancer, and shorter lives, less healthy lives, for our beneficiaries.

The same thing is going to be true for this new preventive benefit. We would like to get our new beneficiaries, when they first

come into the program, to have a different look at Medicare. It is no longer a program that only helps them out after they get sick.

There now is a comprehensive set of preventive benefits that they can use up front to stay healthy, and even if they develop diseases, we are going to help them, for the first time, manage those diseases and prevent their complications.

This is the best way forward to get more money for what we are spending in Medicare and to avoid a lot of the added costs in the program that right now go into pneumonias that could be prevented with vaccinations, to complicated cancers that could be prevented with early detection, to heart attacks that could be prevented by early screening for heart disease, to complications of diabetes like amputations and kidney failure that are extremely expensive that could be prevented by early management, prescription drug use, and better outcomes for the patients involved. This is absolutely critical to the future of Medicare.

Senator BREAUX. I totally agree. Best of luck in getting them done.

Dr. MCCLELLAN. Thank you.

Senator FRIST. Thank you.

Senator Bingaman?

Senator BINGAMAN. Thank you very much for all your testimony.

Let me just ask one other set of questions here. I have been trying to understand parts of this proposed rule. At one page in the rule it states, the Federal Government transfer payments to health plans over and above what would have been paid in the absence of the law, as a result of the provisions of MMA, are expected to total $23.4 billion. Now, that is for the period 2004 through 2009, as I understand it.

On the next page, it says, "As a result of the MMA provisions, we project that in this period, 2004–2009, Medicare beneficiaries enrolling in MMA plans will see benefits beyond basic Medicare A and B coverage, valued at $1.4 billion."

The way I am reading that, we are spending $23.4 billion to get $1.4 billion in benefits to the beneficiaries. What am I missing there? I mean, that does not seem to me a very good investment.

Dr. MCCLELLAN. I do not have that particular page of the regulations in front of me.

Senator BINGAMAN. I will tell you, I read it out of the Federal Register here.

Dr. MCCLELLAN. What I can tell you is what we have seen with out-of-pocket payments for beneficiaries in Medicare Advantage plans in 2004, and what we are projecting going beyond that. For the payment increases that went into Medicare Advantage in 2004, we saw some substantial reductions in premiums. We saw substantial reductions in co-pays.

We saw new coverage which led to beneficiaries savings. And our overall estimates, which are also included in the regulation, show that Medicare beneficiaries who choose Medicare Advantage plans can save more than $700 a year in enrollment in these plans.

Senator BINGAMAN. You talk about $1.4 billion in added benefits. Then you are saying that does not include all of the other savings. Is that what you are saying?

Dr. MCCLELLAN. I think that is right. There are some additional benefits in terms of new covered services and the like, but there also are reduced co-payments, reduced premiums, and other advantages in getting out-of-pocket costs down that are going to a much larger number of Medicare Advantage beneficiaries because these coordinated care plans are going to be more widely available.

Senator BINGAMAN. Could you get back to me, maybe, with a little better sort of analysis as to, if in fact we are investing $23.4 billion, or transferring that much to health plans in this period, could you detail, what are the benefits that beneficiaries receive as a result of that?

Dr. MCCLELLAN. Yes. Absolutely. This has been very important to me because there have been some proposals about not wanting to support Medicare Advantage plans that focus on looking just at the costs of the government and not looking at the overall costs to our health care system. The problem is, because Medicare Advantage plans offer more complete benefits, they allow beneficiaries to get a lot of savings.

So, we can make a lot of progress towards getting total health care costs down through greater access to coordinated care, better prevention, better management of diseases and the like, and that should be our real focus, not trying to save money in Medicare just by shifting costs to Medicare beneficiaries. We need to have more coordinated care to avoid that, to get more money for what we are spending in Medicare, and Medicare Advantage is an important part of that.

We absolutely want to implement the Medicare Advantage provisions in the law in a way that gives the most advantage to Medicare beneficiaries in reducing their out-of-pocket payments, so we will definitely follow up with you on that.

Senator BINGAMAN. I would sure appreciate it. Thank you.

Senator FRIST. Senator Graham?

Senator GRAHAM. Thank you, Senator Frist.

I am now just down to one question before my comment, and it follows up on what Senator Bingaman has been discussing. I think the issue here is one of equity and fairness to both taxpayers and Medicare beneficiaries. Let me make a series of statements of fact, and tell me if I am right, that approximately 89 percent of Medicare beneficiaries currently are being served through a fee-for-service plan.

Dr. MCCLELLAN. Yes.

Senator GRAHAM. That is correct.

According to your own statistics in the Federal Registry, the average person in a Medicare Advantage will get 108.4 percent more in their plan than the average fee-for-service person will receive over an annual basis. Is that correct?

Dr. MCCLELLAN. I am not sure that is exactly correct. I think it varies by area. It also depends on things like the beneficiary's health status.

Senator GRAHAM. That is the statistic that is in the Federal Registry. If it is not correct or if it misstates or fails to cover the——

Dr. MCCLELLAN. Well, I do not want to tell you wrong, so let us go ahead.

Senator GRAHAM. Yes. In that 108.4 percent, is the $12 billion that has been variously referred to as the "discretionary fund" or the "slush fund," is that amount included?

Dr. MCCLELLAN. The fund for making sure that Medicare Advantage plans, and PPOs in particular, go into under-served areas, rural areas? That is not included in that amount.

Senator GRAHAM. I calculate that, if that had been included, instead of being 108.4 percent, it would have been approximately 112 percent above the amount that fee-for-service beneficiaries are receiving. Is that your calculation?

Dr. MCCLELLAN. I have not done the calculation, but I am sure you have got some good math skills in your staff.

Senator GRAHAM. I have your numbers and a calculator. I mean, it is hard to go back to the 89 percent of beneficiaries who have elected to use fee-for-service, and most of them in regions of the country such as mine where there is substantial access to HMOs.

It is not a matter that they elected fee-for-service because they did not have any other choice. They had choices and they decided that they wanted to be able to control who their own doctor was.

They wanted to have more personal control over their health care. Eighty-nine percent have elected fee-for-service. How can you justify paying the HMO plans 112 percent more than you are paying for the fee-for-service?

Dr. MCCLELLAN. Well, I do not think the different is 12 percent, but we will go over that with your staff.What I want to do, is give all beneficiaries access to affordable health care.

Even if there are some differences in payments to Medicare Advantage plans—I think the numbers are somewhat disputed—most important is what is going on with our total health care costs. If beneficiaries are paying more and more out of pocket, we need to do something about it.

The big advantage of the Medicare Advantage plans is that they get those out-of-pocket costs way down. They provide more comprehensive benefits. They coordinate care better. There are things that Medicare's fee-for-service cannot do.

We are putting more money and more effort into fee-for-service through preventive benefits, through chronic care management programs, but the fact is, right now, the Medicare Advantage plans are way ahead in delivering much more efficient health care overall, and that is what we want to help make sure beneficiaries have access to.

Senator GRAHAM. Well, frankly, getting 12 percent more, which, on a $6,000 per beneficiary base is, what, about $700 more per beneficiary per year, they ought to be providing better services.

The question is, why should the Federal Government be subsidizing these plans 12 percent more than fee-for-service in order to deny what most Medicare beneficiaries want, which is a fee-for-service plan?

You know, when we set up these HMO plans, they were supposed to operate on 95 percent of the average of the fee-for-service population within a catchment area, and now we are up to 112 percent. But I would like to use that as the launch to my comment.

I think what we have been talking about today, frankly, is interior decorating. The reality is that there are structural problems in

this program which this Congress, this committee, has refused to deal with. What are those structural problems?

One wall is the integrity wall. Your predecessor is now under a directive to repay the Federal Government a substantial amount of his salary because he violated the law relative to intimidating a Federal employee from telling the Congress what the real costs of this program were going to be.

Another wall was the fiscal wall. We are dramatically overpaying HMOs in terms of the services they are providing. We have a prohibition on using a VA-type negotiating system to get the cost of pharmaceuticals down to a reasonable level, and we are adding substantially to the structural weakness of the Medicare trust fund by these enormous deficits that are being run which are being financed largely from the Social Security and Medicare trust fund.

The third, is the beneficiaries' response. The fact that only 1.8 million Medicare beneficiaries have signed up for the discount card is an indication of wariness as to its value. I would predict that there would be significant wariness when we get to 2006 when beneficiaries start to look at what they are going to get under this prescription drug plan in comparison to what they are paying, and when those who are currently getting a substantial amount of their health care paid through their former employer and they begin to see more and more of those employers begin to terminate or severely restrict their traditional benefits to their retirees.

Those are the questions that we ought to be talking about, not whether the sofa and the lamp are in the right relationships. I know we only have a short of time, Senator Frist, but many of us have been calling for exactly those kind of looks at this program before we go over the cliff in 2006 when it becomes fully operational.

I would hope that, in the days between now and when we conclude this 108th Congress, that we will have that kind of a hearing and be able to look at the big structural problems that this program has and begin to give them some Congressional attention. End of comment.

Senator FRIST. Thank you. I want to really draw this first panel to a close. We will give Dr. McClellan a chance to response, then we will move to our second panel immediately following his remarks, if he has any further comments.

Dr. McClellan, some further comments?

Dr. MCCLELLAN. I want to thank all of you for giving me time to testify here today on these very important issues. We just heard from Senator Graham. There are a lot of strong views on this panel, a lot of different views about the best way forward.

But the most important thing about what we are doing now with our implementation of the new Medicare drug benefit and the new choices for less expensive, more comprehensive coverage in Medicare, is to make sure we are getting all these public comments in so we can provide the most help possible, the most reductions in out-of-pocket costs for beneficiaries, the most increase in support for retiree drug coverage, the most increase in support for preventing illnesses and preventing their complications to get our total health care costs down. We have got the best opportunities to do

this ever, and this has been a very helpful process for making that happen.

I am going to make sure that we keep taking steps to lower out-of-pocket costs, that we implement this effectively, and as part of that we are being absolutely transparent with this Congress.

When we get requests for information we are sending them forward. That includes actuaries' estimates about the impact of the retiree drug subsidy to make sure we are getting the maximum increase possible.

It includes details about estimates of the premium cost, to make sure people know exactly where the money is going in terms of areas where there has been bipartisan support for better physician services and bipartisan support for getting people access to the Medicare Advantage plans that let them lower their out-of-pocket costs substantially right now. I think this is the best way forward, and I look forward to more discussions with this committee.

I look forward to doing as much as we can to give our beneficiaries the help that is overdue. They have been on their own too long with out-of-pocket costs for drugs, prevention, and many other services, and that is changing now and we want to give them the full advantage of all of these new benefits.

Thank you all very much.

Senator FRIST. Good. Thank you, Dr. McClellan.

Senator GRAHAM. Chairman, if I could just make a concluding comment. I am very pleased at what Dr. McClellan just said. I just wish that the statements that you made were not all in the future tense, that we have had the same transparency in the lead-up to adopting this legislation.

Senator FRIST. Thank you.

I would ask the second panel to come forward and we will proceed with them directly. I do want to thank our panel for coming today and testifying before us. The proposed rules are designed to solicit input and comment. We are looking forward to hearing yours this morning.

Our first witness, Karen Ignani, the president and CEO of American's Health Insurance Plans, AHIP, provides through its members health care, long term care, dental, and disability benefits to more than 200 million Americans. Many of their members serve Medicare beneficiaries under the Medicare Advantage program.

Our second witness is Mark Merritt, president and CEO of the Pharmaceutical Care Management Association, PCMA. PCMA members administer pharmacy benefits for more than 200 million Americans.

Next, we have Michael Fitzpatrick who is the executive director of the National Alliance for the Mentally Ill, a nonprofit grassroots organization working for equitable services and treatment for Americans living with severe mental illnesses in their families.

Mr. Fitzpatrick has been with NAMI since the 1990's, serving on both the staff in Maine, and the national office. He also was a member of the Maine legislature, chairing the House Health and Human Services Committee.

Then we will have Gerald Shea, assistant to the president for Government Affairs at the AFL–CIO. Before joining the AFL–CIO, Mr. Shea was with the Service Employees International Union as

an organizer and local union official in Massachusetts, and was also on the staff at the national union's headquarters.

Our final witness, Larry Burton, is the executive director of the Business Roundtable, an association of CEOs of leading U.S. corporations with a combined U.S. workforce of more than 10 million. Prior to this appointment, Mr. Burton was the vice president of External Affairs for BP America.

We will proceed with the witnesses, then open for questioning. Our first witness is Karen Ignani.

STATEMENT OF KAREN IGNANI, PRESIDENT AND CEO, AMERICA'S HEALTH INSURANCE PLANS, WASHINGTON, DC

Ms. IGNANI. Thank you, Senator Frist, Senator Baucus. Our members very much appreciate the opportunity to testify today. As you stated earlier, we participate in the Medicare program, offering services to Medicare beneficiaries in a variety of different ways, from Medicare Advantage, covering almost 5 million beneficiaries, as well as Medigap, covering almost 10 million beneficiaries.

Regardless of which product they offer, our members share the common goal of making Medicare covered services more accessible to Medicare beneficiaries. We do this by providing additional benefits, particularly including out-of-pocket protection, which acts as a safety net for low-income beneficiaries who otherwise might find Medicare's cost containment requirements prohibitive. We stretch beneficiaries' dollars because of the tools we have developed, particularly in the area of prescription drugs.

We offer disease management services. We customize care plans to beneficiaries to ensure continuity of care for the chronically ill, and we have pioneered state-of-the-art techniques that will allow beneficiaries to receive the greatest value from the Medicare prescription drug legislation. We have submitted written testimony on a sample of the Medicare regulatory issues.

I would like to emphasize that we are in the middle of a full-scale effort to understand the implications of the myriad technical issues, and we are working with hundreds of operational leaders around the country in our membership to provide CMS with our best advice on all of these issues by October 4. As soon as we finalize our comments, we will be delighted to share them with the committee.

Today, I would like to share the results of our annual survey of how our member plans will participate in the program next year. There has been considerable discussion about that already.

After years of under funding diminishing the choices to seniors, it is my pleasure to report that we have turned a corner, that the legislation you passed is working, and the fundamentals are in place to accomplish what Congress intended and seniors want.

For the first time since 1998, we are seeing strong projections of increased participation in the opportunities created by the legislation passed last December to better serve beneficiaries.

This announcement comes at a time when millions of seniors and disabled, as Dr. McClellan already indicated, have seen benefits and access to needed prescription drugs, for example, improve this year. In our testimony, we cite the specifics of that.

Looking ahead, Medicare Advantage plans are expanding their offerings to hundreds of new counties in 2005 and anticipating continued growing enrollment thanks to the effects of the MMA.

This turnaround is in addition to the service area expansions already approved by CMS throughout 2004. Since the passage of Medicare legislation, participating plans have expanded choices to beneficiaries in 26 States, providing an additional 9 million beneficiaries with new options.

Another 35 applications are currently under review by CMS. Between February and August, this has resulted in increased enrollment in private sector health plans on a month-to-month basis for the first time in 4 years.

We also know that for 2006 our plans have strong interest in the new options created under the statute, as well as the prescription drug program. Additionally, our survey showed significant interest in the K and L plans for Medigap that were created by the MMA.

We also have an intensive effort under way to make recommendations to Congress from our membership about new ways to provide additional options to beneficiaries under this product that they will be interested in post-2006.

Senator Frist, I would like to thank you for this opportunity to testify. I also would be remiss if I did not take the opportunity to commend CMS on behalf of our entire community for undertaking what is an unprecedented outreach effort to explore the implications of the many complicated operational issues addressed by this legislation, and no community knows and understands that better than ours.

They are doing it fast and they are doing it effectively, and we appreciate the efforts of thousands of people at the agency to develop a workable administrative template that gives beneficiaries the protections that Congress intended to provide them.

Thank you for this opportunity. We look forward to questions.

Senator FRIST. Thank you.

[The prepared statement of Ms. Ignani appears in the appendix.]

Senator FRIST. Mr. Merritt?

STATEMENT OF MARK MERRITT, PRESIDENT AND CEO, PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION, WASHINGTON, DC

Mr. MERRITT. Thank you, Senator Frist. My name is Mark Merritt. I am president and CEO of the PCMA, the Pharmaceutical Care Management Association.

PCMA represents America's pharmacy benefit managers, who represent both independent and stand-alone PBMs and health plans' PBM subsidiaries. With as many as 60 PBMs operating nationally and regionally under a variety of business models, PBMs offer purchasers a wide variety of choices to meet the needs of their plan members.

Together, PCMA members' administered prescription drug plans provide access to safe, effective, and affordable drugs for more than 200 million Americans in private and public programs, including an estimated 65 percent of seniors who have drug benefits through employer- and union-sponsored retiree plans.

Because of the variations among PBMs, it is important that the rules governing Medicare drug plans remain as flexible as possible to encourage maximum participation by PBMs and offer a wide range of choices to beneficiaries.

In a commercial marketplace, PBMs rely upon a broad range of tools and techniques to expand access, promote quality, improve outcomes, and drive down the costs of prescription drugs. PBMs are best suited to manage the drug benefit needs for America's most vulnerable populations, as well.

PMB tools are making a difference. According to a new analysis conducted by Price-Waterhouse Coopers, PBMs drive down the cost of prescription drugs for their clients, on average, by 25 percent, and in 2005 will save $937 per Medicare beneficiary with drug coverage. Other data from the GAO and the CBO have yielded similar findings.

As the administration works together with stakeholders to structure a workable benefit, it is important to preserve PBMs' proven tools and techniques.

With that in mind, I want to touch on a few key issues that we see challenging effective PBM participation in the new Medicare drug benefit.

The first issue relates to formularies. While we believe that the USP's proposed model formulary structure is somewhat overly detailed, it can, nonetheless, serve as a starting point for formulary development.

PCMA believes it is not necessary, however, to expand further the number of categories and classes contained within the USP proposal. For example, formularies in the commercial marketplace with 80 to 90 categories of drugs can provide coverage for 500 or more different drugs.

The second issue is closely related to formularies in regards to pharmacies and therapeutics committees. In developing clinically sound formularies, PBMs rely upon PNT committees to make formulary recommendations.

These committees are largely independent and include a variety of specialist physicians, pharmacists, and others with specific clinical knowledge of drugs and drug therapies.

PCMA has concerns that CMS may consider investing PNT committees with more authority than they are used to managing beyond their areas of expertise, to include financial and administrative management functions.

The third issue we would like to address is e-prescribing. E-prescribing holds the promise of reducing drug-related medical errors and improving safety through the application of enhanced technology. CMS must protect the PBM e-prescribing infrastructure that is the most sophisticated in health care today.

The fourth issue relates to confidentiality of contracting information. Maintaining confidentiality in contracting, including the new Medicare drug benefit, is essential to preserving PBMs' ability to negotiate discounts for consumers and purchasers alike.

Going forward, a clear distinction should be drawn between disclosure of proprietary contracting information and the cost of a prescription to the beneficiary.

Fifth, we need to assure appropriate program oversight and beneficiary protection, not micro-management. Given the extremely short time frame for implementation of the new program, it is critical that the regulations not impose considerable new burdens or require significant changes in the way PBMs currently conduct their business in the commercial marketplace.

Lastly, I want to touch briefly on risk and the stand-alone benefit. PCMA is encouraged by recent comments by the administrator of CMS, Mark McClellan, regarding predictability and encouraging participation and competition in the stand-alone benefit. This, coupled with preserving PBM's existing tools, is the key to maximizing participation in a stand-alone benefit.

Over the next 18 months and beyond, we look forward to making the Medicare prescription drug benefit work as Congress intended and to build on the very best that the private sector has to offer seniors and the disabled.

Senator Frist and Senator Baucus, thank you for the opportunity to testify today. I would be happy to answer any questions you may have.

Senator FRIST. Thank you, Mr. Merritt.

[The prepared statement of Mr. Merritt appears in the appendix.]

Senator FRIST. Mr. Fitzpatrick?

STATEMENT OF MICHAEL J. FITZPATRICK, M.S.W., EXECUTIVE DIRECTOR, NATIONAL ALLIANCE FOR THE MENTALLY ILL, ARLINGTON, VA

Mr. FITZPATRICK. Senator Frist, Senator Baucus, I am Michael Fitzpatrick, executive director of the National Alliance for the Mentally Ill. I am here today on behalf of my organization and its 210,000 members, as well as a number of other organizations, some of whom include the AIDS Institute, the ALS Association, the American Autoimmune Related Disease Association, the Epilepsy Foundation of America, Huntington's Disease, the Latino Coalition, the Lupus Foundation, the National Adult Day Services Association, the Grange, the National Association of Cancer Patients, and Prevent Blindness America.

I want to thank you for convening this hearing and providing us the opportunity to present to this committee the concerns we have regarding patient protections under the new Medicare prescription drug benefit.

The organization on whose behalf I am speaking today have long supported the principal of Medicare reform to include prescription drug coverage. We applaud the efforts in Congress to approve access to pharmaceuticals for our Nation's most vulnerable.

We believe that, when fully implemented, this new benefit will offer unprecedented and long overdue coverage of outpatient prescription drugs for our Nation's seniors. Such coverage is critical to all Medicare beneficiaries, especially those beneficiaries living with disabilities and chronic illness.

In this regard, allow me to briefly highlight a few of our priority issues going forward. Number one, formularies must be defined to enable access to necessary treatments.

In treating Medicare beneficiaries, particularly vulnerable seniors and people with disabilities, physicians often must try many

different drugs of the same pharmacological class before finding one that is the safest and most effective for a specific individual.

In this regard, we are very concerned that the recently issued draft drug classifications developed by U.S. Pharmacopoeia, coupled with the language in the recently issued prescription drug benefit proposed rule, may not provide adequate access to all necessary medications.

As noted earlier, the proposed rule only requires that two drugs be covered in each class. Thus, the range of classes becomes a critical benchmark for the range of drugs that enrollees and their doctors will have access to.

We believe the classifications set forth in the draft USP guidelines may create confusion and could be used by prescription drug plans to discourage enrollment of certain beneficiaries, such as the Medicare beneficiaries with severe disabilities and chronic illnesses with higher treatment costs.

Further, the 146 classes in the draft guidelines offer prescription drug plans the option to exclude entire classes of medication that are now commonly prescribed to seniors and people with disabilities, including the statins, anti-convulsants, and selective serotonin reuptake inhibitors, the SSRIs.

The SSRIs, for example, are collapsed into a single class with the older tricyclic medications that are now widely recognized as being outdated and antiquated treatment options.

Another potential problem faced by beneficiaries living with chronic illnesses are provisions in the regulations that allow prescription drug plans to change their formularies in the middle of the plan year. Such changes are allowed so long as the plans provide appropriate noticed, defined in the regulations, of 30 days.

We believe that this is insufficient notice and does not recognize the real-world crucial nexus between drug plan choice and access to vital medications for beneficiaries.

Medicare beneficiaries are locked into one plan for an entire year and may have specifically chosen the plan based on its formulary. We believe the agency should, at a minimum, require that the plans grandfather coverage of product medications until the next open enrollment period.

While this approach would still permit plans to use bait-and-switch marketing strategies involving popular medications, it would provide the most vulnerable beneficiaries on established medications the ability to continue their existing treatment regiment without having to pursue coverage through the plan's appeal process.

Number two. Pharmacy and therapeutic committee operations should be transparent and reflect an independent assessment of all coverage restrictions.

The statute outlines very basic standards for the development of formularies by prescription drug plans' pharmacies and therapeutic committees for the composition of such committees, but grants CMS considerable latitude to establishment guidelines to make the process sensitive to the specific needs of beneficiaries.

To ensure that all coverage policies are based on objective clinical rationale, CMS should implement rules to make explicit the PNT committee's responsibilities to restrictive coverage policies.

We also recommend limiting the number of voting PNT committee members with conflicts so to avoid diluting the voices of independent members.

Three, the regulation should incorporate patient protections for therapeutic substitution. We believe that CMS should incorporate in the final regulations patient protections of therapeutic substitution, and a particular requirement that the prescription drug plans not engage in such practices without the express consent of the prescribing physician.

The preamble supports such a requirement, but is not included in the actual regulation. At a minimum, the regulation should require the plans to defer to State laws on therapeutic substitution.

Preserving the physician's role in the prescribing process is an important beneficiary protection, particularly for vulnerable Medicare populations who may be on multiple medications and living with many co-morbidities.

Four, CMS should provide detailed guidelines for alternative benefit designs that ensure the beneficiaries receive access to needed therapies. It is imperative that CMS vigorously enforce the requirement in the law that prescription drug plans not implement alternate plan designs.

We are very concerned that the alternate schemes designed primarily to reduce costs could impede patient access to medically optimal medicines and could be used to cherry pick only the healthiest enrollees.

Vulnerable participants would be particularly at risk of plans engaged in such practices. The proposed rules allow for the review of tiered cost sharing and categories and classes in the formulary, but does not clarify what the review will be.

We urge CMS to closely scrutinize applications to provide alternative benefit packages and place reasonable limits on the cost sharing requirements. A prescription drug plan could employ an alternate tiered co-payment benefit package. CMS should also require plans to maintain consistent cost sharing arrangements across all therapeutic classes. Finally, we believe the regulations should ensure access to off-label medications.

Five, CMS should implement special protections for dual eligibles. We also believe that the final regulation should address the unique problems faced by beneficiaries who qualify for both Medicare and Medicaid, the so-called dual eligibles.

These individuals are vulnerable because of low incomes, specifically a large percentage of the dual eligibles; by some estimates, as many as 40 percent are living with severe mental illness or other disabilities.

To protect these, and all low-income individuals, CMS should enforce a continuity of care requirement to ensure access to the same medications that are available under Medicaid. At a minimum, dual eligibles should be allowed to continue on medications they are currently taking and not be required to switch to another drug.

In addition, under existing Medicaid law, dual eligibles could not be denied access to their medications if they are unable to pay their co-payments.

Senator FRIST. Mr. Fitzpatrick?

Mr. FITZPATRICK. Yes?

Senator FRIST. Let me ask you to summarize the points, and then we will ask questions when we come back. I want to make sure that we get through the rest of the panel, then during questions we would be happy to come back. But if you could just summarize.

Mr. FITZPATRICK. Thank you.

Well, let me stop here. I can defer to the rest of the panel and be open for questions.

Senator FRIST. Your complete statement, we have, and it will be made a part of the record as well.

Mr. FITZPATRICK. Absolutely. Thank you.

[The prepared statement of Mr. Fitzpatrick appears in the appendix.]

Senator FRIST. Mr. Shea?

STATEMENT OF GERALD SHEA, ASSISTANT TO THE PRESIDENT FOR GOVERNMENTAL AFFAIRS, AFL–CIO, WASHINGTON, DC

Mr. SHEA. Thank you, Mr. Chairman. I also want to thank Chairman Grassley and Senator Baucus for the invitation to present to you today.

In my written submission, I touch on a number of issues, some of which are the core structural issues that have risen in various parts this morning. But in my oral presentation, I want to restrict my comments to the implementation of the benefit as it affects employer-provided care.

Retirees. One in four Medicare beneficiaries gets employer-sponsored prescription drug benefits. It is the largest single source until this point, with the introduction of the Medicare benefit itself. My comments are based on the experience of our 60-some unions who negotiate for 13 million active members and 3 million retirees, altogether well over 40 million covered lives.

It is no secret that high health costs and the resulting competitive issue among businesses has made this the number one problem in collective bargaining, and indeed a conflictual point in any employment setting.

Despite a lot of hard work between employers and unions, and not just a few strikes over this issue, in fact, we are seeing the steady erosion of employment-based benefits.

The sharpest edge of that problem is retiree coverage. So, quite apart from the basic point that Medicare needed to be updated in the ways that Dr. McClellan and others said, with the addition of this benefit, this is very important to the employment-based system.

How it gets implemented is very, very important, because a mistake in the implementation could potentially, as some people have predicted, lead to an even more rapid loss of coverage.

Now, the complicated design of this benefit poses certain problems for writing regulations and for employers and unions in figuring out how to integrate this new benefit and the subsidy with existing benefits. We appreciate CMS's very aggressive outreach to us and to employers, and Karen has mentioned this as well.

We are participating with them very actively in a dialogue about this implementation. We are working with our National unions and

we will be providing very comprehensive comments before the October 4 deadline.

Overall, we fully support the department's statement in the proposed regulation to: (1) provide flexibility for plan sponsors; (2) to protect retiree benefits; and (3) to make sure there are no windfalls that go to employers because of the substantial money involved.

But to actually reach these goals, we are going to need detailed guidance in the final regulations. That is the first major substantive point I would make. We appreciate the opportunity for input. We just hope that the final rule does provide very specific guidance, because we fear without that there could be real implementation bumps, as we say.

Specifically, I wanted to make the following substantive points. One, the actuarial test needs to be carefully chosen so as to make sure that there is not the possibility that employers could get a subsidy and not provide much of a benefit. Even in CMS's own words, the single prong test, so called, could create that, possibly, and we think it is totally unacceptable.

Second, we think, to be consistent with the Congressional intent as we read it, CMS must require employers to provide at least as much financing for the health benefits as they get from the subsidy. But that is a question that is really not clear, at least in the draft regulation, and we have discussed this with the CMS officials a number of times.

Third, employers should demonstrate that the subsidy is actually allocated to health benefits in a way that is transparent and accessible to retirees.

There are several other technical problems which I allude to in my testimony. They are not insignificant, but I will not spend time on them here because I want to finish with one final point, and that is further on the transparency issue.

The regulation will rely on attestation, but it does not have access to the underlying actuarial assumptions on which the attestation will be based, nor does it have a provision at this point for retirees or their representatives being able to challenge that in some way, or at least investigate it to see if what is being alleged is actually the case.

We think that kind of a protection for retirees would go a long way towards ensuring that the intent of this legislation is actually met.

Thank you, Mr. Chairman.

[The prepared statement of Mr. Shea appears in the appendix.]

Senator FRIST. Thank you, Mr. Shea. I appreciate all the panelists. You are bringing up so many great ideas, and also the written statements, which we will all be studying in real detail, I know are much more specific. But we appreciate all of the comments.

Mr. Burton?

STATEMENT OF LARRY BURTON, EXECUTIVE DIRECTOR, BUSINESS ROUNDTABLE, WASHINGTON, DC

Mr. BURTON. Thank you, Senator Frist, Chairman Grassley, Ranking Member Baucus, and all members of the committee for giving me the opportunity to testify on this important issue.

I am executive director of Business Roundtable, an association of chief executive officers of leading corporations with a combined workforce of more than 10 million employees in the United States, with $4 trillion in annual revenues.

Our companies alone provide health care coverage to approximately 25 million people. Rapidly rising health care costs are a challenge for families and individuals. These costs are creating a major drag on economic growth for American companies and our country.

Health insurance premiums have increased at a double-digit pace each of the past 3 years, and premiums for employer-sponsored health coverage for families rose 11.2 percent in 2004, which is about five times the rate of inflation.

Additionally, more than half of Roundtable member CEOs have identified rising health care costs as the most significant cost pressure facing their companies. That is why a major priority for the Roundtable is to promote policies that help reduce health care cost burdens and strengthen the system of market-based health care coverage for millions of American workers and their families.

This brings me to the three points I want to share today. First, Business Roundtable believes that the Medicare Modernization Act is a strong step toward addressing some of the challenges of our health care system. We support the MMA because it encourages employers to continue providing retiree health care coverage.

Second, implementation of the law is challenging for employers, unions, health plans, and PBMs, so it is crucial that the rules are finalized so that the marketplace develops in a quick fashion. This will allow our employers to make the best and most informed decisions about how they may continue offering retiree coverage.

Finally, the Roundtable believes it is important to educate seniors and their families about the benefits of this complex law. There is widespread misperception about what employer-sponsored retiree coverage is. Companies that provide health coverage to their retirees over the age of 65 offer benefits that exceed those offered under the traditional Medicare program. The companies' extra benefits wrap around the traditional Medicare benefit. In other words, they supplement traditional Medicare coverage.

The flexibility of this new Medicare law allows employers to continue to coordinate their extra benefits with Medicare. My written testimony goes into detail on implementation of the reform and how important it is to get implementation done quickly. We urge CMS to move swiftly and we support their efforts to make this new system work.

Finally, I want to emphasize the importance of communicating the benefits of the Medicare reform to retirees, their families, and friends. Until retirees understand the law, they cannot make informed choices. This spring, the Roundtable commissioned a study to determine the value of this benefit for seniors.

The study detailed the State-by-State value of the prescription drug discount card and the drug benefit, revealing $24.1 billion in valuable new drug benefits for seniors.

Because this benefit will only be realized if seniors take advantage of it, we then undertook an effort to communicate about the Medicare benefit and reform.

Since May, Business Roundtable has been conducting a national consumer education effort to inform American seniors of the benefits available to them.

In conjunction with this education campaign, the Roundtable also produced several educational materials to help communicate the benefits of this new Medicare plan. With your permission, I would like to offer these materials for the record.

Senator FRIST. All right.

[The information appears in the appendix.]

Mr. BURTON. We want to continue improving health care coverage for America's seniors and encouraging employers to continue providing coverage.

We look forward to continuing to work with CMS to expedite the implementation process and we support all efforts to communicate its benefits to seniors. Business Roundtable will continue to work with all stakeholders to ensure effective implementation.

Thank you very much for allowing me to be here today.

Senator FRIST. Thank you.

[The prepared statement of Mr. Burton appears in the appendix.]

Senator FRIST. I thank the entire panel, and their patience for what I know has been a long hearing and lengthy testimony over the course of the morning. Again, we look forward to both discussing and reviewing all of the materials provided to us in greater detail.

I have a single question to Mr. Fitpatrick. Thank you for your support of the MMA. In your testimony, you mentioned that given the way that the USP draft model guidelines are structured, plans will likely just cover cheaper drugs, older drugs, for example, the selective serotonin reuptake inhibitors, the SSRIs.

In reading that and listening, I just want to ask you, are you sure of that? It seems to me, just looking from afar, that a lot of the newer drugs are covered in the commercial market today, in which there are fewer requirements for formularies. This addresses the whole issue which we are all interested in, in balancing access and appropriate access with affordability.

Mr. FITZPATRICK. We were concerned, looking at the initial draft guidelines, that they seemed to create a class within the anti-depressant group that would allow plans the option of only including the older tricyclates, or perhaps a generic medication, not recognizing that there have been revolutions in the treatment of antidepressants, and certainly the SSRIs are more widely used simply because of the issues around side effects and efficacy.

So what we are certainly advocating for is certainly more access, and certainly allowing physicians to prescribe the full range of medications. So, that was largely our concern.

Senator FRIST. All right. Thank you.

Senator Baucus?

Senator BAUCUS. Thank you. Thank you, Mr. Chairman.

Mr. Merritt, you have heard Dr. McClellan say that he does not expect there to be a fall-back plan because all of these PDPs and insurance companies, everybody is going to offer stand-alones, or people are going to participate in the other plans, the MMAs, and so forth.

Now, so far, it is my understanding that there has been no commitment by the private industry to commit to stand-alone plans. What do you need to know? Have you seen the regulations now? They have come out. Earlier, I think your organizations were waiting to see what the regulations would be. Now you have seen them. Are you going to participate? Is Dr. McClellan correct, there will be no fall-backs?

Mr. MERRITT. Well, we still need to see the final rule. First of all, there are a varied number of companies in our industry. Some are insurer-owned PBMs, some are stand-alone PBMs. All of them will certainly be subcontractors in the stand-alone benefit. It is too early for us to tell.

Senator BAUCUS. What do you need to know?

Mr. MERRITT. Well, I think we need to know a lot of stuff. We have concerns about how USP and how the formularies are finally going to end up. Are all of our tools going to be protected? What is the prescribing going to look like?

Obviously risk is an issue, but there is a broader issue of, just generally, are we going to be able to do the things that have made us a success in the commercial marketplace. So, we need to look at the final rule, which will be out in February.

Senator BAUCUS. Right. What do you see in the proposed that you like, and what do you see that you do not like? I mean, without taking too much time. And what questions would you like answered? You said you would like to see. Well, that does not help us very much.

Mr. MERRITT. Sure. Yes.

Senator BAUCUS. But what questions would you like answers to?

Mr. MERRITT. Sure.

Senator BAUCUS. Precise questions.

Mr. MERRITT. All right. First of all, what we want, is you asked about the things we like and do not like. The thing we like, is the fact that this is centered around PBMs and around a competitive marketplace. That is good for us, obviously. We have general issue concerns.

Specifically, we want to know how formularies are going to be managed, and we do not know that yet. We need to know how grievances and appeals are going to be managed as well. Are we going to have the same confidentiality standards that we have had in the discount card and the funded benefit?

In the proposed CMS rule in the preamble, it talks about PNT committees having broad authority. Yet, PNT committees have basically a clinical job, which they do very, very well for PBMs. What is going to be their role exactly?

Are we going to be able to do the cost management side, as well as the clinical side, the way that we really need to? E-prescribing is on a different track, but that is not totally done yet and we need to see how that works out.

Also, generally speaking, this is new for us. This is a very short time frame for us to get all of this together and start making commitments.

Senator BAUCUS. Right.

Mr. MERRITT. I think we showed clean hands during the discount card, that we did a lot in our companies to comply with that and

get on board very, very quickly, and it took a lot of work and a lot of resources.

Senator BAUCUS. What is your best guess? Will there be fall-back plans?

Mr. MERRITT. I do not know if what Administrator McClellan has said is true, and it is very encouraging if it is, then I think you are going to see participation to do the stand-alones and I am not sure you are going to need a fall-back. But that is premature of me to say as well.

Senator BAUCUS. When do you think you will know?

Mr. MERRITT. I am not sure, frankly, I am going to know before this final rule is really done in January or February. We may hear hints of it, but also, as somebody running a trade association, it is a very competitive issue. These CEOs are not calling me and saying, I am going to play, I am not, because it has huge implications for how they are perceived in the marketplace.

Senator BAUCUS. Ms. Ignani, your reaction to my basic question. Will plans participate? Will PPOs?

Ms. IGNANI. We know that a number of our members are looking very, very seriously at participating in all of the new products that will be offered beginning in 2006.

To amplify what Mr. Merritt is saying in terms of what we do not know now that we are going to be probing with CMS, and will be in our recommendations and our final regulation submission on October 4, are several areas that I think will be relevant, and have been relevant to the previous discussion, Senator Baucus.

First, the issue of two drugs per class. There are namely two drugs, as you know, so we have to sort through from the perspective exactly as you have suggested, balancing access, but at the same time cost containment when we know that essentially there are combinations that do essentially the same things where there are generic substitutions and the doctor feels comfortable having that used.

ow does that play out? How does it play out from the standpoint of some of the new information coming forth on particular drugs. So is that a barrier to actually achieving the proper balance and putting the fulcrum in the right area from the perspective of the beneficiary?

Senator BAUCUS. What is your best guess? How many PPOs are really going to participate here?

Ms. IGNANI. I think, to try and answer your question very honestly, there are hundreds of operational issues. So are you asking me the question about PPO participation or are you asking me about PDP, prescription drugs?

Senator BAUCUS. I am asking about both, because you are involved with both.

Ms. IGNANI. All right. Well, let me separate the two.

Senator BAUCUS. Yes.

Ms. IGNANI. And I will not bore you with a lot of the technical details with respect to the USP. But I do think Mr. Merritt is right in suggesting that there are a number of things we do not know, and ultimately we hope that the USP itself, and ultimately CMS, will look at the recommendations in light of what is going on now

in coverage for prescription drugs for the under 65. I think that offers a number of lessons in terms of this balance.

In terms of participation, our members are very much interested in providing services to beneficiaries all across the country. We have stated that in our testimony.

How the regulations finally get developed in terms of the operational issues, we will be able to answer very specifically the question of who is participating, and when.

What we have been devoted to in talking with hundreds of people around the country who are administering these programs on the ground, is to try to get from them their best judgments about what needs to happen in order to make the operational issues workable.

CMS has done an extraordinary job of outreach and we are working very, very hard to make sure not only are we providing information from Washington, but people in the trenches are offering information.

Senator BAUCUS. How do you feel about all of this? Is there enough time to do it reasonably well to sort out all these issues?

Ms. IGNANI. I must say, had you asked me this question back in January, I would have been very, very surprised that CMS could have gained the ground that it did.

In a short period of time, we are now, August, eight months after the passage of the legislation, putting out 900 pages of regulation that basically, I think everyone is saying, is an excellent starting point to give us the opportunity now to dialogue with them on particular operational issues.

They have accomplished something monumental, and Dr. McClellan deserves a great deal of credit for that, but so do the thousands of people who are in Baltimore and Washington and around the regions, because they have worked together and they have worked very hard.

So, I think it is the beginning of a workable framework. We are probing very, very specifically questions that will be very important in terms of running these programs and doing what you expect.

Senator BAUCUS. Mr. Shea, do you think there is enough time to do this right? Do you feel good about it, or not good? Just in general.

Mr. SHEA. We are very nervous. We think CMS has really put a lot of effort into this. The outreach has been terrific. We really are nervous and afraid, frankly, that if the rule comes out without sufficient guidance, companies and unions are going to be lost trying to implement this.

Senator BAUCUS. Yes. That is a concern of mine, too, frankly.

Mr. SHEA. And the issue that is most directly our concern, is that this is going to provide some momentum to further reduce retiree coverage, exactly the opposite of what it was intended to do, shore up retiree coverage, and simply because of the fact that there is a Medicare benefit, employers who want to get rid of this coverage because of the very high costs involved—I am not saying they do not have legitimate concerns—want to turn this cost over to the employees, and they are going to say, there is a Medicare benefit out there.

Senator BAUCUS. What is the best way to ensure that the employees get a fair deal here?

Mr. SHEA. I think the suggestions I made are the ones that we have now, and I am sure we will refine them over the next few weeks, about requiring transparency in terms of what the benefit is and how the subsidy is used, and making sure the subsidy is actually used on health benefits, and in demonstrating that to the employees and their representatives.

Senator BAUCUS. Ms. Ignani, how many people, beneficiaries, are needed geographically to make a plan work?

Ms. IGNANI. I do not think there is an ideal number, actually, but I do think the indigenous rules are very, very important. How do they work? Network adequacy, Senator Baucus, is one, for example that we comment on in our testimony and we have had considerable dialogue with this committee about.

That is an area where, in many cases, we are not able to secure contacts with facilities, hospitals, physician groups that have monopoly situations in many rural areas.

And so to the extent CMS can provide a little flexibility as we meet the basic standards, but where we provide evidence that folks are unwilling to contract, that is a very good example of something that is standing in the way of participation because you cannot run a health plan, you cannot offer services, if you do not have a provider network.

The flip side of that is, in many parts of the country, particularly in rural areas, we have many facilities that are insisting on 140 to 180 percent of fee-for-service, payments in that arena. So, we have a number of issues that relate to network adequacy.

So, how they draw those rules, for example, will depend very definitely on how many plans can participate, because our plans want to set up networks across the area, whatever the area boundaries will be.

Senator BAUCUS. So what is a fair number of geographic areas or regions? What is a fair number of regions? It was 15 to 50.

Ms. IGNANI. We say in our testimony that this is probably one of the most difficult issues because we have members, for exmaple, who come from two perspectives. One, we have the perspective of plans that are local-based plans, State-based plans.

Senator BAUCUS. I know it is difficult. So what is the answer?

Ms. IGNANI. I am coming to that. I am actually going to give you an answer.

Senator BAUCUS. All right. All right.

Ms. IGNANI. I do not mean to prolong this unnecessarily.

Senator BAUCUS. Right.

Ms. IGNANI. And they have suggested the 50 State approach. Others who work across the country are looking at the operational issues inherent in doing more States rather than fewer.

I think that one of the ways to begin to approach this is to begin with 50 States, with incentives for individuals to do more. We have talked to CMS about that sort of approach. There are other ways to do that. Dr. McClellan suggested some of the operational issues in his testimony that had been flagged by plans that are interested in providing services across more than one State.

Senator BAUCUS. Well, boy, I will tell you, you have partly answered my next question, but we have not had a good experience

in Montana. We had an HMO a while ago, and it left. We do not have a lot of people in our State.

Ms. IGNANI. I think, as you know well, Senator Baucus, one of the problems with the services that had been offered in Montana was, in fact, the inability to sustain the provider network. That is where a PPO is particularly desirable for hospitals that do not have the experience accepting risk. They do not have the mechanism to do that. They are more interested in PPOs.

I have noticed that in 2004, I took a look at the pending applications and the newly approved applications, and we have a number of managed fee-for-service products, particularly in rural areas around the country, and hospitals are indicating they are more comfortable, again, with that. They do not have to have the ability to accept risk to enter into contractual relationships. So, we are trying to do as much as we can with as many products as we can to meet that Congressional expectation.

Senator BAUCUS. Well, I do not have any other questions.

Before we leave here, does anybody have anything to say? I mean, has anybody said something that is so outrageous that it deserves an answer, or some point that you would like to rebut anybody here, generally? Anybody? Mr. Shea?

Mr. SHEA. I do not want to get into a back-and-forth, but I do want to make note, referencing an earlier conversation when Dr. McClellan was here.

There were at least two significant quality improvement steps taken from our point of view in the MMA. One, the incentive for hospitals to be reporting relative performance data in order to get the full update, and the announcement was made from CMS last week that 3,900 hospitals are now reporting the full 10 measures. We cannot stop there. That is just the beginning of public reporting.

Senator BAUCUS. Right. I agree.

Mr. SHEA. The second thing is the very small provision, but a significant one, is to begin the process of providing, whether it is clinicians, consumers, or plan sponsors, with comparative effectiveness information.

This is critical to getting the decision making structure in place. We cannot sustain the system in its current cost configuration. The employers cannot pay for it. I do not think the Federal Government can pay for it.

We have to, as many people have agreed, change the system in terms of the key delivery process. A lot of people, from employers to health plans—CMS, I would point out, is the leader in this—are working on the solutions to this. One key, key step is getting data, independent, reliable data, on comparative effectiveness among prescription drugs.

Senator BAUCUS. I agree with that. Does anybody disagree? I mean, if we are going to address the cost of health care we have got to get comparative data and start addressing quality.

Ms. IGNANI. Senator, I think Mr. Shea has made one of the most important points, because we know that 50 percent of what is done in health care is not evidence-based. So, we need to have comparative data to understand what is going on.

Senator BAUCUS. Who is doing some of the best work, and how do we get moving?

Ms. IGNANI. Jack Wenburg.

Senator BAUCUS. Good.

Ms. IGNANI. Elliot Fisher at Dartmouth.

Senator BAUCUS. Yes, he is good.

Ms. IGNANI. The IOM has done considerable work. The Health Care Forum is trying to aggregate all this information. But this is a very, very important point. People need to know not only what is spent, but what we are spending on.

Senator BAUCUS. I would encourage all of you, and anybody else who might be listening, to kind of take the bull by the horns here and begin to develop ideas on how to address this, because the sooner we get at this, the more likely it is that we are going to start to have some honest, meaningful solutions to the increased health care costs in this country. There is an opportunity for all of us here. There is an opportunity for each of you, as well as these other organizations.

Mr. SHEA. And passage of the patient safety legislation, which I think has been 6 years in the works, was really a big, big step this past summer. We certainly hope that the conference committee is able to get this done and get it to the President's desk.

Senator BAUCUS. All right. Well, thank you very much for your participation and your patience.

Chairman Grassley would like for me to announce that the record will remain open until the close of business Friday. I would encourage everybody to follow that.

The hearing is adjourned. Thank you.

[Whereupon, at 12:55 p.m., the hearing was concluded.]

APPENDIX

Additional Material Submitted for the Record

Prepared Statement of Larry Burton

Introduction

Thank you, Chairman Grassley, Ranking Member Baucus, and all members of the committee for giving me the opportunity to testify today on this important issue.

I'm Larry Burton, Executive Director of Business Roundtable, an association of chief executive officers of leading corporations with a combined workforce of more than 10 million employees in the United States and $4 trillion in annual revenues. Our companies alone provide health care coverage to approximately 25 million people.

Rapidly rising health care costs are a challenge for families and individuals. These costs are creating a major drag on economic growth for American companies, and our country. Health insurance premiums have increased at a double-digit pace each of the past three years. Premiums for employer-sponsored health coverage for families rose 11.2 percent in 2004, which is about five times the rate of inflation.

Additionally, more than half (58%) of Roundtable member CEOs have identified rising health care costs as the most significant cost pressure facing their companies.

That is why a major priority for the Roundtable is to promote policies that help reduce health care cost burdens and strengthen the system of market-based health care coverage for millions of American workers and their families.

Which brings me to the three points I want to share here today.

1. First, Business Roundtable believes that the Medicare Modernization Act (MMA) is a strong step toward addressing some of the challenges of our health care system. We support the MMA because it encourages employers to continue providing retiree health care coverage.
2. Second, implementation of the law is challenging for employers, unions, health plans, and Pharmacy Benefits Managers (PBMs) – so it is crucial that the rules are finalized so that the marketplace develops in a quick fashion. This will allow our employers to make the best and most informed decisions about how they may continue offering retiree coverage.
3. And finally, the Roundtable believes it is important to educate seniors and their families about the benefits of this complex law.

Medicare Modernization Act

There is a widespread misperception about what employer-sponsored retiree coverage is. Companies that provide health coverage to their retirees over the age of 65 offer benefits that exceed those offered under the traditional Medicare program. The company's extra benefits "wrap around" the traditional Medicare benefit – in other words, they supplement traditional Medicare coverage.

With the dramatic rise in health care costs over the past few years, sustaining employer-sponsored retiree coverage has been difficult. In fact, over the past 15 years, the number of medium and large companies offering employer-sponsored retiree health benefits has reduced by half. Typically, though not universally, these plans offer generous health benefits that simply supplement the current Medicare program, including the new prescription drug benefit. Today, about 12 million seniors – one in three – have supplemental Medicare coverage through their employers.

A May 2003 survey found that of the 65 Business Roundtable companies that responded, all offer retiree benefits that supplement Medicare. The benefits average $2,333 per year per beneficiary, of which an average of $1,498 is spent on outpatient prescription drug

coverage. Retiree plans use PBMs or private insurers to manage these prescription drug benefits. Employers have a vast array of expertise in offering retiree health care benefits and in driving quality improvements through innovation.

Given these factors, the Roundtable supports the MMA for the following reasons:

1. It provides options for employers to continue providing retiree health care coverage to retirees;
2. It recognizes that an employer-sponsored retiree plan is "group" coverage and, as such, certain requirements such as geography, premium, and payment may be modified through a waiver process; and
3. It contains important steps toward providing all consumers with certain information on cost and quality.

Medicare Modernization Act Regulations

The Center for Medicare & Medicaid Services (CMS) rules provide further context for the law's employer-sponsored retiree plan options. Employers are likely to choose to continue to offer benefits as follows:

Employers who offer drug benefits to their retirees who are eligible for prescription drugs could:

(1) Provide prescription drug coverage through employment-based retiree health coverage. If employment-based retiree health coverage is at least actuarially equivalent to the standard prescription drug coverage, the sponsor would be eligible for a special Federal subsidy for each individual;

(2) Contract with a PDP sponsor or Medicare Advantage (MA) organization to enroll Medicare beneficiaries covered under the retiree plan into a prescription drug plan (PDP) or Medicare Advantage-prescription drug (MA-PD) plan. Alternatively, the sponsor itself could apply to be a PDP sponsor or MA organization and offer a PDP or MA-PD plan to its retirees. Employers could offer drug coverage that is more generous than that offered under the standard prescription drug coverage under Medicare Part D.

(3) Provide prescription drug coverage that supplements, or "wraps-around," the coverage offered under the PDP or MA-PD plans in which their retirees (and retiree's spouse and dependents) enroll.[1]

All of these options continue to involve the employer in offering some form of retiree health care coverage, and it's important to note that these options still equate to offering that coverage. The flexibility of this reform allows employers to continue to coordinate their extra benefits around the Medicare benefits offered to their retirees.

Implementation Issues

In order to implement the employer provisions of the MMA, the final rules must be promulgated so that employers can accurately assess their options, and contracting prescription drug or Medicare Advantage plans can finalize their strategies such that a marketplace exists for employers. At this point in time, employers do not know what entities will be offering PDP plans and Medicare Advantage plans, so it is essential for CMS to move quickly in addressing these implementation issues.

Furthermore, employer plans need full flexibility to select from the options offered by the law – receiving a subsidy; electing and enhancing benefits offered by a Prescription Drug Plan; or enrolling beneficiaries in a Medicare Advantage plan. Business Roundtable companies have, on average, seven different retiree plans.

Implementation is a complex issue that requires health insurers and PBMs to work with employers and human resource managers. We urge CMS to move swiftly and we support their efforts to make this new system work.

Medicare Education Campaign

Turning now to my final point, I want to emphasize the importance of communicating the benefits of the Medicare reform to retirees, and their families and friends. It is critical that they have information to allow them to make informed choices.

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[1] Fed. Reg. Vol. 69, No. 148, Tuesday, August 3, 2004

This spring, the Roundtable commissioned a study to determine the value of this benefit for seniors. The study detailed the state-by-state value of the Prescription Drug Discount Card and the drug benefit, revealing $24.1 billion in valuable new drug benefits for seniors.

Because this benefit will only be realized if seniors take advantage of it, we then undertook an effort to communicate the message about the Medicare benefit and reform. Since May, Business Roundtable has been conducting a national consumer education campaign to inform America's seniors of this new option and benefits available to them as part of the new Medicare law.

In conjunction with this education campaign, the Roundtable also produced several educational materials to help communicate the benefits of the new Medicare plan. A brochure called *10 Things You Should Know About the New Medicare Prescription Drug Benefit,* newsletter articles, and handouts were created to assist companies in presenting information to their current and former employees. With your permission, I offer these materials for the record.

Again, let me emphasize the importance of working together to ensure that retirees have clear, concise information about this new law.

Conclusion

In conclusion, we believe that the MMA is an important step forward in improving health care coverage for America's seniors and encouraging employers to continue providing coverage. We look forward to continuing to work with CMS to expedite the implementation process, and we support all efforts to communicate its benefits to seniors.

Business Roundtable will continue to work with all stakeholders to ensure effective implementation.

Testimony of Larry Burton
before the Senate Finance Committee
Hearing on "Implementing the Medicare Prescription Drug Benefit and Medicare Advantage Program: Perspectives on the Proposed Rules"
September 14, 2004

Questions & Answers

Question from Senator Grassley

1. In the past, many large employers offered Medicare+Choice plans to their Medicare-eligible retirees. Unfortunately, as you know, many plans had to withdraw from the program due to insufficient funding. The Medicare Modernization Act (MMA) took significant steps to remedy that situation under the Medicare Advantage program.

   What do employers and retirees find attractive about Medicare health plans? Do you think employers will work to offer these plans to their retirees again?

A. Many large employers did offer Medicare+Choice plans to their Medicare-eligible retirees. As a result of reduced funding for the premium, many plans exited key marketplaces making this a less attractive market for many employers. Business Roundtable supported the MMA provisions that strengthened the Medicare Advantage program. MMA plans are expanding at this time due to the provisions of MMA. We are aware that some employers are evaluating Medicare Advantage as an important option for their retirees in the future.

Question from Senator Baucus

1. Mr. Burton, what is the best way to define actuarial equivalence? What is the best way to ensure that existing retiree coverage is maintained and that the subsidy is only paid to employers that provide coverage equal or greater than the standard Medicare benefit?

A. In its proposed rule, CMS defines "actuarial equivalence" as "equivalent values demonstrated through the use of generally accepted actuarial principles and in accordance with section 1860D-11(c) of the Act and §423.265(c)(3) of this part." 69 Fed. Reg. at 46635. Business Roundtable supports this type of broad definition, not wedded to any single methodology, for a number of reasons.

   First, we believe that this flexible approach of incorporating generally accepted actuarial principles fosters the legislative goals of attracting a significant segment of the employer sector, thereby maximizing the number of employers eligible for the drug subsidy, while preventing windfalls for employers who do not provide a benefit that is at least equivalent to the Medicare benefit.

Second, a flexible approach, such as the one adopted in the proposed rule, reduces transaction and compliance costs, both at the public and private levels, and makes timely implementation realistic.

We do not support the use of a fixed value test because the value will be dependent upon the nature of the plan design and the expected utilization of benefits under the plan. Furthermore, we believe that employers should only count the employer contribution toward the plan in evaluating whether the plan qualifies for the subsidy.

Michael J. Fitzpatrick
Testimony Before the Senate Finance Committee
Hearing on the Medicare Prescription Drug, Improvement and Modernization Act of 2003 Regulations
September 14, 2004

I. Introduction

Mr. Chairman and members of the Committee, I am Michael Fitzpatrick, Executive Director of the National Alliance for the Mentally Ill (NAMI). I am here today on behalf of my organization and its 210,000 members and 1,200 affiliates, as well as:

- ALS Association,
- American Auto-Immune Related Diseases Association,
- Epilepsy Foundation of America,
- Huntington's Disease,
- The Latino Coalition,
- Lupus Foundation,
- Men's Health Network,
- National Alliance for Caregiving,
- National Adult Day Services Association,
- National Grange of the Order of Patrons of Husbandry,
- National Coalition for Women with Heart Disease,
- Prevent Blindness America, and
- RetireSafe.org.

Mr. Chairman, I want to thank you for convening this hearing and for providing us the opportunity to present to this Committee the concerns we have regarding patient protections under the new Medicare prescription drug benefit.

The organizations on whose behalf I am speaking today have long supported the principle of Medicare reform to include prescription drug coverage, and we applaud efforts in Congress to improve access to pharmaceuticals for our nation's most vulnerable citizens. We hope that that, when fully implemented, this new benefit will offer unprecedented – and long overdue – coverage of outpatient prescription drugs for our nation's seniors. Such coverage is critical to all Medicare beneficiaries, but it is especially important to those beneficiaries from vulnerable populations, such as those living with disabilities and chronic illnesses. We are committed to working with CMS and this Committee to ensure that the new law and its implementing regulations provide the intended coverage and protection to Medicare beneficiaries. In this regard, allow me to briefly highlight a few of our priority issues going forward.

II. Formularies Must Be Defined to Enable Access to Necessary Treatments

In treating Medicare beneficiaries, particularly vulnerable seniors and people with disabilities, physicians often must try many different drugs within the same pharmacological class before finding the one that is the safest and most effective for a specific individual. Physicians must consider a drug's side effects and efficacy, patient co-morbidities, and possible interactions with other drugs the beneficiary may be taking,

which, of course, can vary greatly from patient to patient. Further, it is not uncommon for a drug to be initially effective for a patient, but to subsequently lose efficacy, thus requiring the physician to begin the search again. Consequently, it is critical that physicians treating Medicare beneficiaries have access to a wide array of medications.

In this regard, we are concerned that the recently issued draft drug classification guidelines (the Guidelines) developed by the U.S. Pharmacopeia (USP), coupled with language in the recently issued prescription drug benefit Proposed Rule (Proposed Rule),[1] may not provide adequate access to all necessary medicines. Because the Proposed Rule only requires that two drugs be covered in each class,[2] the range of classes becomes a critical benchmark for the range of drugs that enrollees and their doctors will have access to. We believe the classifications set forth in the Guidelines may create confusion and could be used by prescription drug plans to discourage the enrollment of certain beneficiaries, e.g., Medicare beneficiaries with severe disabilities or chronic illnesses who have higher treatment costs.

For example, the Guidelines divide the category of antidepressants into three classes, one of which is reuptake inhibitors.[3] Selective serotonin reuptake inhibitors (SSRIs) and Selective Norepinephine Reuptake Inhibitors (SNRIs) are not segregated as distinct classes, but are instead collapsed into this single class with older tricyclic medications that are now widely recognized as outdated and antiquated treatment options. However, because of the way prescription drug plans can use the Guidelines to restrict access, it is reasonable to assume that many plans will choose to offer two older tricyclic medications as the only treatment option for depression for their enrollees. Likewise, in the case of anti-epileptic drugs used to treat seizures, USP failed to divide the category of anti-convulsants into any classes whatsoever. This means that USP's draft Model Guidelines would only require health plans to cover two drugs, or 10% of the currently available seizure medications.

We also are concerned that restrictions on the numbers of classes and categories of drugs, as proposed in the USP Guidelines, could discourage the development of new prescription medications. For example, manufactures would have little incentive to produce new drugs if formularies already satisfy the minimum two drugs per class requirement by providing access to older medications. There is little financial incentive to pursue these medications if there is a more than reasonable chance they would be excluded from formularies.

Consequently, CMS should require plans to provide clinical coverage for more than two drugs per class, if clinically appropriate. Since clinically inappropriate limits on certain classes could adversely impact the quality of care Medicare beneficiaries receive,

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[1] 69 Fed. Reg. 46,632 (Aug. 3. 2004).

[2] See 69 Fed. Reg. at 46,660.

[3] See Medicare Prescription Drug Benefit Draft Model Guidelines, Drug Categories and Classes in Part D, United States Pharmacopeia (Aug. 2004).

CMS should address the need for coverage of an appropriate range of therapeutic options in the final regulations. To its credit, CMS is seeking comments on ways to balance the needs of the mentally ill and other vulnerable patient populations with the need for flexibility by prescription drug plans.[4] We plan to respond to the agency's request with information demonstrating the importance of requiring broad access to medications so that physicians have the flexibility to prescribe any necessary drug. We urge the Committee to take an active role in overseeing the new benefit to ensure that CMS fulfills its obligations under the MMA.

We are also concerned that the process by which the USP Expert Committee developed the Guidelines was not open to groups representing Medicare beneficiaries living with severe disabilities and chronic illnesses. In June, eight patient groups, including NAMI, requested a meeting with USP staff to offer input into the process of developing the Guidelines. This request was made in writing through a formal letter that was signed by the groups. Unfortunately, we never received a formal response from the USP staff. After several follow-up phone calls, we were informed that neither the Expert Committee nor the USP staff would be meeting with patient organizations in advance of the August 27 public meeting.

At the same time, we understand through press reports that USP staff and the Expert Committee have been holding formal and informal meetings with other stakeholders. We are also frustrated that appointments to the Expert Committee that were to represent the interests of beneficiaries did not include organizations representing beneficiaries with chronic illnesses. While we respect the need for the Expert Committee and USP staff to develop these Guidelines free of influence from the diverse array of stakeholders in the new drug benefit, we feel strongly that this process has been tilted to restrict meaningful input from the stakeholder who is most at risk, i.e., the Medicare beneficiary who will depend on the new drug benefit for access to life-saving and life-sustaining treatment. We strongly urge this Committee to exercise its oversight authority to ensure that CMS does not adopt final Guidelines that fail to consider the needs of the most vulnerable beneficiaries.

Another potential problem faced by chronically ill, mentally ill, and other vulnerable Medicare beneficiaries under the new benefit is the provision of the MMA that allows prescription drug plans to change their formularies in the middle of the plan year.[5] Such a change is allowed so long as the plans provide "appropriate notice" to affected beneficiaries and other stakeholders prior to removing a covered drug from a formulary or changing its cost-sharing status.[6] "Appropriate" is defined as 30 days in the Proposed Rule.[7] We strongly believe that this is insufficient notice and does not recognize the real world, crucial nexus between drug plan choice and access to vital medicines for beneficiaries. Medicare beneficiaries are locked into one plan for an entire year and may

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[4] See id. at 46,661.

[5] See 42 U.S.C. § 1395w-104(b)(3)(E).

[6] See id.

[7] See id.

have specifically chosen the plan based on its formulary. Beneficiaries who cannot obtain the same treatment due to a formulary change may fail to complete their treatment regimens, thus increasing other Medicare costs if more expensive medical interventions are subsequently required.

If CMS believes that it cannot limit prescription drug plans in this manner, the agency should at a minimum require that plans "grandfather" coverage of chronic medications until the next open enrollment period. While this approach would still permit plans to use "bait and switch" marketing strategies involving popular medicines, it would provide the most vulnerable beneficiaries on established medicines the ability to continue their existing treatment regimen without having to pursue coverage through the plan's appeals process.

Relying on the most vulnerable populations – including those who are chronically ill, mentally ill, or enrolled in long-term care facilities – to successfully and in a timely way navigate the appeals process to obtain drugs that previously were covered as a matter of course is not a realistic option. Many may be unaware of, or not understand, the appeals process and instead turn to less effective therapies or stop their treatments altogether. For these populations, these concerns are exacerbated by their condition, making it critical that these beneficiaries be allowed to continue receiving their drugs under existing terms, without having to pursue an appeal.

III. Pharmacy and Therapeutic Committee Operations Should Be Transparent and Reflect an Independent Assessment of All Coverage Restrictions

As you know, the MMA outlines very basic standards for the development of formularies by prescription drug plan pharmacy and therapeutic (P&T) committees and for the composition of such committees, but grants CMS considerable latitude to establish guidelines to make this process sensitive to the specific needs of beneficiaries.

One important way to protect these interests is for CMS to require participating P&T committees to provide the public and their members with advance notice of their meeting agendas and to accept public input on drug coverage decisions. P&T committees should accommodate such input both during the development of policies, and after the policies have been finalized in draft form, but before implementation. Such a requirement would help CMS ensure that P&T committees comply with the MMA requirement that coverage decisions be based "on the strength of scientific evidence and standards of practice, including assessing peer-reviewed medical literature."[8]

Additionally, this process will ensure that beneficiary protections for coverage decisions under the new drug benefit parallel those protections provided by the public comment process in the traditional Medicare program for developing national and local coverage policies. P&T committees should also be required to document and explain the reasons for their formulary decisions and make these determinations public. This would ensure that the P&T Committee follows the intent of Congress and makes clinical, rather than financial, judgments when developing a formulary.

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[8] See 42 U.S.C. § 1394w-104(b)(3)(B).

To ensure that all coverage policies are based on objective, clinical rationales and are developed by clinical experts, CMS should also implement rules making explicit that P&T committee responsibilities extend beyond the development of simple formularies to include the development of all restrictive coverage policies. In the preamble to the Proposed Rule, CMS states that it interprets the MMA as "requiring that a P&T committee's decisions regarding the plan's formulary be binding on the plan."[9] In addition, CMS states that it expects "P&T committees will be involved in designing formulary tiers and any clinical programs implemented to encourage the use of preferred drugs (e.g., prior authorization, step therapy, generics programs)."[10] However, these provisions are not included in the actual regulations, but are only discussed in the preamble. We urge CMS to include these requirements in the regulations themselves to ensure that prescription drug plans understand their obligations. As noted above, the rationales and clinical justifications for these coverage policies should be subject to discussion and validation in an open forum with an appropriate opportunity for public input, including input from patient advocacy organizations.

CMS also is seeking additional public comment on the important issue of P&T committee independence.[11] In this regard, we strongly recommend limiting the number of voting P&T committee members with conflicts so as to avoid diluting the voices of independent members. The recent settlement of the government's investigation of Merck-Medco Managed Care provides guidance in this regard.[12] Pursuant to that agreement, a majority of P&T committee members must be actively practicing physicians, pharmacists, or health care professionals and not be employed by Medco,[13] thus limiting the risk that conflicted members will marginalize the input of independent members. This protection should be incorporated into the regulations.

IV. The Regulations Should Incorporate Patient Protections for Therapeutic Substitution

CMS should incorporate in the final regulations patient protections for therapeutic substitution and, in particular, a requirement that prescription drug plans not engage in such practices without the express consent of the prescribing physician. In the preamble to the Proposed Rule, CMS indicated that it supports such a requirement,[14] but neglected to include it in the regulations. We urge CMS to expressly include such a standard in the final regulations, or, alternatively, to expressly state that plans should defer to state laws

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[9] 69 Fed. Reg. at 46,659.

[10] Id.

[11] See id.

[12] See United States v. Merck-Medco Managed Care, Civil Action No. 00-737, Consent Order of Court for Permanent Injunction (E.D. Pa.)

[13] See id.

[14] 69 Fed. Reg. at 46,667 ("Therapeutic substitution would always require explicit prescriber notification and approval.").

on therapeutic substitution. As you may be aware, many states have laws requiring prescriber consent before plans may make a substitution.

Preserving the physician's role in the prescribing process is an important beneficiary protection, particularly for vulnerable Medicare populations who may be on multiple medications and living with many co-morbidities. We believe that the patient-physician relationship in these situations is sacrosanct and should not be undermined by any implication that therapeutic substitution can be executed without explicit physician consent.

V. CMS Should Provide Detailed Guidance for Alternative Benefit Designs to Ensure That Beneficiaries Receive Access to Needed Therapies

It is imperative that CMS vigorously enforce the requirement under the MMA that prescription drug plans not implement alternative plan designs – such as alternative tiered cost-sharing schemes – if "the design of the plan and its benefits . . . are likely to substantially discourage enrollment" by certain Medicare beneficiaries.[15] In this regard, we are very concerned that alternative schemes designed principally to reduce costs could impede patient access to medically optimal medicines and could be used by plans to "cherry-pick" only the healthiest enrollees. Medicare beneficiaries – particularly those living with chronic illness and severe disabilities – would be particularly at risk if plans engaged in such practices.

In the Proposed Rule, the Secretary states it will review "tiered cost-sharing, the use of categories and classes in a formulary, and the choice of drugs provided in each category," but does not state what the standard of review will be.[16] We plan to request that CMS further clarify the standards by which it will review benefit design for discriminatory effect. and that, in particular, it consider the following recommendations.

In general, we urge CMS to closely scrutinize applications to provide alternative benefit packages. To avoid the potential for favorable selection and ensure that patients and their providers can reasonably access different therapeutic choices – particularly, drug therapies that target vulnerable populations – we recommend that CMS place reasonable limits on the cost-sharing requirements a prescription drug plan could employ in alternative, tiered co-payment, benefit packages. Specifically, we recommend that the agency consider a maximum limit on cost-sharing differentials and that a beneficiary's co-payment never be allowed to be greater than one-half of the plan's cost for the drug. Further, to avoid adverse selection problems, we urge CMS to require plans to maintain consistent cost-sharing requirements across all therapeutic classes. By including these protections, CMS would help ensure that the most vulnerable beneficiaries do not face discriminatory co-payments that are markedly higher than those faced by individuals with other conditions and disease states.

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[15] See 42 U.S.C. § 1395w-111(e)(2)(D)(i).

[16] See 69 Fed. Reg. at 46,680.

Prescription drug plans should also be required to specifically address the issues of adverse selection and beneficiary access to care in their applications to provide alternative benefit packages. CMS should make public its analyses and an explanation of its final decisions to approve or disapprove these applications. These reports should specifically address the agency's findings on the issues of favorable selection and access. Publicizing the analyses and explanations regarding CMS' decisions will ensure public oversight of plan benefit designs and the ability of vulnerable populations to access the drug benefit prescribed by Congress.

The regulations must also ensure that Medicare beneficiaries have access to the latest treatments approved by the FDA. This is particularly important for vulnerable populations, such as people with ALS, for whom emerging treatments could significantly improve the treatment of their conditions. Standards must be established that recognize emerging medicines and provide an opportunity for these medications to be included in formularies in a timely manner. Additionally, patients should have access to these new therapies while they are being reviewed for inclusion on a formulary. In this way, formularies should be flexible, not only meeting the needs of the patients of today, but also those of tomorrow by providing timely access to new medications, while at the same time ensuring continued innovation.

Finally, we believe that the regulations must ensure access to "off-label" medications as necessary. Off-label use of prescription drugs is common practice in the care and treatment of patients with complex chronic conditions. For example, there are no medications approved by FDA with primary indications to treat lupus. Therefore, proper care of lupus patients requires physicians to prescribe multiple medications off-label. In its proposed rule (might only be in preamble...must check cite) CMS directs prescribers to clearly document and justify off-label use in their Part D enrollees' clinical records. Unintentional oversight of off-label treatments can lead to dire consequences in vulnerable populations, denying medications to frail patients or instituting additional barriers to access. Further, attention must be given to evidence-based off-label usage in formulary development. A plan may chose to cover more than two drugs in a given therapeutic class, but since the plan is not required to cover drugs per off-label use, essential medications could be omitted from the formulary.

VI. CMS Should Implement Special Protections for Dual Eligibles

We also believe the final regulations should address the unique problems faced by beneficiaries who qualify for both Medicare and Medicaid (so-called "dual eligibles"). These individuals are particularly vulnerable because of their low incomes. Significantly, a large percentage of dual eligibles (by some estimates as many as 40%) are living with severe mental illnesses and other disabilities.

Currently, these beneficiaries are receiving their drugs under Medicaid. To protect these and all low-income individuals, CMS should enforce a "continuity of care" requirement to ensure access to the same array of mental health and other medications that are available under Medicaid. At a minimum, dual eligibles should be allowed to

continue on the medications they are currently taking and not be required to switch to another drug.

In addition, under existing Medicaid law, dual eligibles cannot be denied access to their medications if they are unable to pay their co-payments. While the co-payment for any single drug may be nominal, beneficiaries taking multiple drugs may face multiple co-payments which in the aggregate can pose a substantial financial burden. Consequently, it is imperative that this Medicaid protection be included in the new Medicare drug benefit so that beneficiaries who cannot pay their co-payment are not denied access to necessary medications.

VII. Beneficiaries Should Have Meaningful Appeal Rights

To ensure that beneficiaries' rights are protected, the final regulations should provide meaningful grievance and appeal procedures for denials of coverage and improper conduct by prescription drug plans. We have a number of concerns with regard to these appeal procedures, not the least of which is their utter lack of clarity in establishing different processes and procedures for challenging different kinds of plan decisions. In general, we believe that CMS should endeavor to clarify these highly important procedures, so that beneficiaries and their families are fully aware of their rights under the new benefit.

We are also concerned that, under the Proposed Rule, it is unclear when a decision is considered to be a coverage determination that requires a specific written notice with appeal rights and, in particular, whether a denial of a drug as a non-formulary drug at the pharmacy counter would constitute such a coverage determination. Without a written notice of appeal rights, the beneficiary may never realize that an additional step is required to trigger the appeals process. Consequently, CMS should clarify the Rule to require that a notice of coverage determination be issued at the time the prescription is denied at the pharmacy and that such notice include an explanation of the beneficiary's appeal rights.

Next, CMS should clarify that beneficiaries have the right to de novo review of denials of coverage and exception requests before an independent review entity (IRE). Specifically, CMS seems to treat IRE reconsiderations arising from formulary exception requests differently from those arising from other coverage determinations. CMS states that an IRE, when reviewing an appeal of a denial of a formulary exceptions request, is limited to determining whether the prescription drug plan properly applied its own formulary exceptions criteria and that "the IRE would not have any discretion with respect to the validity of the plan's exception criteria or formulary."[17] This limited review is not supported by the MMA. CMS should clarify in the final rule that it does not intend to limit the scope of IRE review.

Third, beneficiaries with chronic, mental, and other debilitating illnesses must be able to obtain rapid responses to their appeals and not have to navigate multiple

[17] Id. at 46,721.

procedures. Under the MMA and Proposed Rule, to obtain a non-preferred drug on the same cost-sharing terms as a preferred drug, the prescribing physician must demonstrate that the preferred drug "either would not be as effective . . . or would have adverse effects."[18] Similarly, to receive coverage for a non-formulary drug, the prescribing physician must demonstrate that "all covered Part D drugs on any tier of the formulary . . . would not be as effective for the individual as the nonformulary drug [or] would have adverse effects for the individual."[19]

This second showing necessarily encompasses the determination that the preferred formulary drug is not as effective as the non-formulary drug or would have adverse effects on the individual. Therefore, it would not make sense to grant preferred cost-sharing status to a second or third tier drug for which the beneficiary had demonstrated medical necessity, but not grant similar treatment to a non-formulary drug for which the beneficiary had made a similar showing. Patients should be able to obtain both coverage and preferred status in one appeal.

Further, assuming a beneficiary is successful in an appeal to obtain coverage or preferred status for a drug, the plan appears to have complete discretion to determine the beneficiary's cost-sharing obligations.[20] A beneficiary who obtains coverage of a necessary drug but cannot afford the plan-established cost-sharing has wholly illusory appeal rights. We strongly urge CMS to establish reasonable parameters for the cost-sharing obligations of beneficiaries who file successful appeals.

Finally, CMS should clarify the scope of the plan decisions that are appealable. To ensure that appeal rights are meaningful, the appeal provisions should apply to the full scope of coverage denials – including denials of requests for prior authorization.

VIII. Conclusion

Mr. Chairman, we appreciate that Congress has taken an enormous first step toward providing a comprehensive outpatient prescription drug benefit to Medicare beneficiaries. CMS has built on that effort in its proposed regulations, but much work needs to be done to ensure that this benefit is robust and successful and that beneficiaries have the safeguards they need and deserve. We pledge to continue working with you and with CMS to provide assistance, feedback, and information in every way we can to develop a meaningful Medicare prescription drug benefit that protects the interests of all beneficiaries. Thank you again for allowing me the opportunity to present our views. I am, of course, prepared to answer any questions you may have.

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[18] 42 § 1395w-104(g)(2); see also 69 Fed. Reg. at 46,720.

[19] 42 § 1395w-104(h)(2) (emphasis added); see also 69 Fed. Reg. at 46,721.

[20] See 69 Fed. Reg. at 46,721, 46,844.

Question from Chairman Grassley

1. In your testimony, you state that you had a number of concerns about the appeal procedures and that CMS needs to clarify the procedures in the final rules. What specifically do you think CMS needs to do?

Answer
To appeal adverse determinations or exception decisions, beneficiaries must request plans to review their decision again and make a redetermination within 30 days unless the beneficiary paid out-of-pocket for the medication at issue, in which case the plan has 60 days to decide. Even if a plan honors a request to expedite a redetermination, the deadline for plans to make a decision could be as long as 14 days. Further, following a redetermination, beneficiaries may appeal to an independent review entity for a reconsideration of their case, but these entities will not be authorized to review or question the criteria plans use to evaluate exceptions requests. The proposed rules do not even set deadlines for reconsideration decisions. Finally, after receiving a reconsideration decision, beneficiaries are only allowed to appeal to an ALJ if the amount in controversy meets a threshold level of $100, and it is unclear how CMS will calculate whether a beneficiary has met this threshold.

Consequently, the exceptions process and the requisite mechanisms to effect it, will fail respecting the need for timely and clinically appropriate access. NAMI recommends that CMS create a special exceptions process for this population. Such a would require only physician attestation (dispense as written) or comparable certificate of medical necessity to accompany those prescriptions not on the PDP formulary in accordance with the statutory definition of medical necessary services at 42 U.S.C. § 1395(y).

CMS should also expand section 423.600 (a) to allow not only the enrollee, but also the enrollee's authorized representative or the prescribing physician to file a written request for reconsideration by the Independent Review Entity (IRE). There are beneficiaries who simply do not have the physical or mental capability to craft a written response. Just as CMS has suggested that an enrollee, the enrollee's authorized representative, or the prescribing physician on behalf of the enrollee may request a standard coverage determination or expedited redetermination, these individuals should also be allowed to request a reconsideration with an IRE.

NAMI would also like to suggest that expedited requests be resolved by plans within 24 hours of receipt and within 3 hours in long-term care facilities. It would also be helpful if a prescribing physician is allowed the discretion as to whether an expedited request is warranted. Under the proposed regulations, PDPs are allowed 14 days to consider an exceptions request with an additional, optional 14 days available as an extension. As such, a standard exceptions request may take up to a month to come to a resolution. Such a long delay in determining an initial exception is simply too long for the standard case. Moreover, such a delay in ruling on an exceptions request could have serious consequences for beneficiaries whose health may be in jeopardy while awaiting a response.

Physicians should be the first and final determiner of the necessity for expedited exceptions request. This meets Congress' intent as stated in 1860D-4(g)(2), specifically: "...the prescribing physician determines that the preferred drug for treatment of the same condition either would not be as effective for the individual or would have adverse effects for the individual or both." In addition, many federal and state regulations require that long-term care pharmacists dispense medications within three hours of the order being written. A lengthier approval process would force these entities to be in violation of their legal requirements.

Moreover, in the event that exceptions requests or coverage determination appeals are unsuccessful, beneficiaries should be allowed a special election period to enroll in a different plan offering the drugs prescribed by the physician. This special election period should be limited to 30 days during which the drug(s) in question should continue to be supplied by the plan denying the exception request/coverage determination. It is important to note that the proposed regulations already make provisions for a special election period in the event that an exceptions request and all subsequent appeals are denied. Specifically,

Section 423.36 (c)(8)(ii) makes clear that individuals may change plans if "the individual meets other exceptional circumstances as CMS may provide." Following the same logic for continued drug coverage during appeals, a 30-day window should be established in which beneficiaries continue to receive adequate drug supply until they can enroll in a new plan offering them the ability to continue on the prescribed therapy.

Finally, a continued supply of the drug(s) in question need to be guaranteed at the previous tiered price sharing level by a plan while an exceptions request is under consideration. Since an exceptions request requires the physician's determination that the requested treatment and not the preferred drug treatment is required for effective and safe therapy, plans should continue to supply the drug in question during the entirety of appeals process in order to protect the health of the beneficiary. Such drugs should be afforded to the beneficiary at the previous tiered price level, if applicable, as before the mid-year change. Increasing the financial burden on an enrollee during the appeals process may represent a de facto denial of appropriate medication if the enrollee lacks the financial means to continue the prescribed medication during the appeal. Such a denial may potentially culminate in adverse outcomes and increased total healthcare expense.

Not only does a continued drug supply provide needed protections for enrollees, it also motivates plans to quickly resolve exceptions requests. Without such a mechanism, plans may lack the direct financial incentive to meet the appellate timelines required of them and instead may inadvertently or purposefully lengthen the time for resolving an exceptions request at the expense of beneficiary's health.

Question from Senator Baucus

1. Mr. Fitzpatrick, the 2003 Medicare bill sought to balance the tension to between providing access to medically-necessary drugs and appropriate cost containment. In your respective opinions, do the Title I regulations appropriately strike this balance?

Answer
NAMI remains hopeful that this balance will be found. However, the proper balance between access and cost containment can only be reached in the final regulations if CMS adheres to the congressional intent contained in the Medicare bill and implements its own suggestion in the NPRM preamble to permit special needs populations, such as those with mental illness, access to an open formulary. These beneficiaries often must confront cognitive impairments and other symptoms of their illnesses that limit their ability to ability to select the appropriate plan and assess the drugs on each plan's formulary (i.e. including whether or not it is an open formulary). As a result it is necessary to ensure that these beneficiaries receive the proper medications. It is imperative that CMS view its mission of striking the balance between cost containment and access as viewing overall costs to Medicare and Medicaid, not just drug expenditures.

In order for CMS to ensure meaningful access to medically necessary prescription medications, there are several critical public policy challenges for enrollees with mental illnesses that must be addressed in the final regulations, including but not limited to:

- access to the medicines deemed medically necessary for proper treatment by the prescribing physician;
- timeliness of beneficiary access to these medicines;
- continuity of care for enrollees stabilized on a specific pharmaceutical regimen; and
- alignment of incentives for all relevant stakeholders that include CMS, prescription drug plans (PDPs), prescribing physicians and patients.

The final regulations represent an important opportunity to achieve these important public policy objectives and to assure success of the program for all interested parties.

NAMI supports the well established congressional intent that CMS place a high priority on ensuring that elderly and dually eligible Medicare beneficiaries with mental illnesses have clinically appropriate access to medically indicated pharmaceuticals under the new prescription drug benefit. Congress, in enacting the MMA, was explicit in their expectation of pharmaceutical coverage for patients with mental illness and

specifically directed CMS to pay special attention to the needs of Medicare beneficiaries with mental illnesses and to ensure that they have "clinically appropriate access to pharmaceutical treatments for mental illness," In addition, the conferees pointed out that those patients with severe mental illnesses are "a unique population with unique prescription drug needs as individual responses to mental health medications are different." Conference Report accompanying the Medicare Prescription Drug, Improvement and Modernization Act, Report No. 108-391, pp.769-770 (emphasis added).

In addition, CMS, in the preamble to the NPRM, specifically requested that groups representing vulnerable populations with unique medical needs comment on the best mechanism to provide clinically appropriate access to these populations. CMS states that while traditional formulary management techniques should be employed by prescription drug plans (PDPs),

"it is possible that certain vulnerable populations (enrollees in long-term care facilities or those suffering from mental illness ... for example) may be negatively impacted financially if they do not have access to a wide range of drugs in certain therapeutic classes and categories. We seek comments on ways to balance plans' flexibility to use some of the mechanisms described above to . . ." 69 Fed. Reg. at 46,661

At this point, NAMI remains hopeful that the final regulations will uphold Congressional intent and sufficiently protect beneficiaries with mental illnesses, while recognizing the increased costs that the Medicare & Medicaid systems will incur if this patient population does not have open access to medication. Weak protections for beneficiaries with mental illnesses will result in increased costs for both the Federal government and state governments.

Several studies have indicated that pharmaceutical cost savings achieved through restricting access to drugs can result in a greater increase in non-drug related costs. For example, among patients with schizophrenia, restrictions on the number of medications resulted in increased use of acute mental health services and increased medical treatment costs, as well as pain and suffering on the part of patients. *(Soumerai SB, et al. Effects of limiting Medicaid drug-reimbursement benefits on the use of psychotropic agents and acute mental health services by patients with schizophrenia. NEJM 1994;331:650-655).* While this study involved caps on the number of prescription drugs, which is expressly forbidden by the MMA statute, prior authorizations, PDLs, and other mechanisms to decrease drug cost by restricting access may produce similar results. While Medicare may face some of the increased non-drug costs, states may suffer the most through increased non-drug costs from potential relapses of individuals with mental illnesses resulting in either institutionalization in a state mental health center or incarceration in a state-run facility.

Frequent Formulary Changes

A PDP can effectively remove or add a specific drug to its formulary once a month except for the time period between the start of the annual coordinated election period and 30 days after the beginning of the contract year. Such frequent formulary changes may negatively impact state finances because removal of drugs from the formulary may disrupt continuity of care, potentially resulting in increased societal costs related to nontreatment and relapse. Continuity of care may be maintained through special election of a new plan covering prescribed treatment, by the states (but not Medicaid), or by another entity providing funding for the drugs themselves. However, under the current proposed rules, this extra funding does not appear to either qualify as wraparound coverage nor count toward the individuals' true out-of-pocket (TrOOP) expenditures. As such, a state may be faced with funding 100% of this drug expense while a dual-eligible languishes in a perpetual donut hole. It is NAMI's belief that formulary deletions should only occur once per contract year, except for new information regarding a particular drug's safety.

These are just a few of the components that must be addressed in the final regulations to ensure that patients have access while balancing costs. The statute provides CMS the authority to adequately protect vulnerable patients while also providing plans the flexibility to aggressively negotiate with manufacturers for lower process. CMS's implementation of the law will determine whether congressional intent is upheld and the appropriate balance is found between costs and critical access for vulnerable beneficiaries to the medications they need to achieve stability and recovery.

Questions from Senator Bingaman

1. Ensuring Dual Eligibles Receive Appropriate Access to Drugs: Almost all states have recognized the unique needs of individuals with mental illness and provided exemptions for mental health medications including antipsychotics and antidepressants while employing cost-saving techniques. Physicians are currently able to prescribe medicines to their dual eligible, special-needs populations. When passing the MMA, Congress did not intend to diminish benefits for dual eligible beneficiaries with mental illnesses. After January 1, 2006, what steps should CMS and the Congress take to ensure continuity of care and access to necessary treatment for these special needs patients?

Answer
NAMI believes that it is imperative for the Final Rules to explicitly recognize that vulnerable dual eligible beneficiaries are typically receiving complicated treatments that are specifically tailored with individualized drug therapies. Such treatments often take into account the individual's current medical condition, past treatment history, likely response to side effects, other medications currently being taken, expense, any co-morbid illnesses, and safety in overdose given heightened risk of suicide.

As a result it is essential that dual eligible beneficiaries – especially those with severe mental illnesses – be able to access existing medications that are best suited to their treatment needs and that are most likely to produce optimal treatment outcomes. In NAMI's view, a "continuity of care" requirement is the most effective means for achieving the goals of ensuring a smooth transition to the Part D drug benefit for dual eligibles and maintaining access to effective treatments that ensure clinical stability. Such a "continuity of care" requirement would require drug plans that enroll dual eligibles – either voluntarily or through the Secretary's default enrollment authority – to ensure access to the same array of medications that they are currently being prescribed under Medicaid. Such a requirement would prevent drug plans from switching dual elgibles to alternative preferred agents on the plan's formulary.

In addition, under existing Medicaid law, dual eligibles should not be denied access to their medications if they are unable to remunerate for their co-payments. While the co-payment for any single drug may be nominal, beneficiaries taking multiple drugs may face multiple co-payments that in the aggregate, can pose a substantial financial burden. Consequently, it is imperative that this Medicaid protection be included in the Final Rules so that beneficiaries who are unable to meet their co-payment responsibilities are not denied access to necessary medications.

2. Dual Eligibles Appeals Rights: Dual eligible beneficiaries currently have due process rights for claims related to their Medicaid coverage. Some of these rights appear to be weakened by the proposed rule. For example, Congress intended that Medicaid beneficiaries have the right to continued access to needed medical care while their appeal is pending – to make sure they are not left without access to a needed prescription pending a dispute with their plan. It doesn't appear to me that this standard is met by the proposed rule. What steps do you think that CMS and the Congress should take to ensure protections for these vulnerable citizens?

Answer
Dual eligible beneficiaries currently have due process rights for claims related to their Medicaid coverage. Some of these rights appear to be weakened by the proposed rule. For example, Congress intended that Medicaid beneficiaries have the right to continued access to needed medical care while their appeal is pending – to make sure they are not left without access to a needed prescription pending a dispute with their plan. It is far from clear that this important standard is included in the proposed rule.

In terms of the steps necessary to ensure protections for these vulnerable beneficiairies, NAMI is recommending that CMS create a special exceptions process for this population. CMS should require only a physician attestation or comparable certificate of medical necessity to accompany those prescriptions not on the PDP formulary in accordance with the statutory definition of medical necessary services at 42

U.S.C. § 1395(y). Essentially, a physician writing "dispense as written" should be sufficient for providing access to the medication(s) for this population.

Question from Senator Hatch

1. In the proposed rule for Title I, CMS specifically states that it is possible that certain vulnerable populations, such as those suffering from mental illness may be negatively impacted financially if they do not have access to a wide range of drugs in certain therapeutic classes and categories. CMS requested comments regarding any special treatment, for example, offering certain classes of enrollees an alternative formulary that accounts for their unique medical needs as well as suggestions regarding the particular special populations for whom CMS may want to make allowances. How will an alternative flexible formulary provide access for beneficiaries with special needs referenced in the preamble to the proposed rule?

Answer
NAMI is extremely concerned that the NPRM appears to allow substantial discretion for Medicare prescription drug plans to use restrictive utilization management techniques, including prior authorization, tiered co-payments, "fail first" requirements and step therapy. Given the overwhelming evidence demonstrating the dangers associated with such practices to individuals with mental illnesses, we believe protections are needed. NAMI is grateful for the recognition of these challenges in the NPRM and the need for special exemptions from these techniques for certain beneficiaries, including those with mental illness.

As the NPRM notes:
"We request comments regarding any special treatment (for example, offering certain classes of enrollees an alternative or open formulary that accounts for their unique medical needs, and/or special rules with respect to access to dosage forms that may be needed by these populations but not by other Part D enrollees), we should consider requiring of plans with respect to special populations, as well as suggestions regarding the particular special populations for whom we may want to make allowances." 69 Fed. Reg. at 46,661

In response to this request, NAMI has requested that the final regulations include a requirement for prescription drug plans to incorporate an alternative, flexible formulary for enrollees with mental illness into their benefit designs. This formulary would provide access to the full array of medications to treat mental illness (without use of "fail first" requirements, prior authorization, step therapy, therapeutic substitution, or any similar restrictive policies). Eligibility for this alternative, flexible formulary would be restricted to enrollees diagnosed with a mental illness (including dual eligibles). Instead of imposing the burden of cost control on these vulnerable beneficiaries, utilization management would be carried out using policies that focus on improving the prescribing behavior of providers.

This alternative, flexible formulary would instead focus utilization management on practices designed to improve (or at least maintain) the clinical status of individual plan enrollees. Among the advantages and opportunities associated with this recommended alternative, flexible formulary are: 1) integration of provider peer education initiatives designed to improve clinical practice, 2) closer scrutiny and retrospective review of individual clinicians to address instances of "polypharmacy" or other inappropriate prescribing, 3) enhanced data review to identify fraud, deviation from clinical best practice, outlier prescribers, and inappropriate dosing levels, and 4) cost containment through techniques such as targeted case management of chronic illness to improve coordination of care and outcome measurement.

In NAMI's view, restrictive practices such as prior authorization, fail first, and step therapy are both inappropriate and unnecessary for people with mental illnesses. Medications to treat mental illness are generally not interchangeable, including those with the same mechanism of action, and differ in how they affect brain chemistry. It must be recognized that these illnesses themselves are highly variable in terms of symptoms and their impact on individual patients, and physicians must carefully tailor drug therapies to each individual to take into account the patients' current medical condition, past treatment history, likely response to side effects, other medications currently being taken, expense, any co-morbid illnesses, and safety in overdose given heightened risk of suicide.

Limits on access to appropriate medications and delays that inevitably result from policies such as prior authorization can cause relapses and can impair the ability of individuals to achieve recovery. Moreover, these policies may also impose a significant risk of death since persons with depression or schizophrenia are at a significantly higher risk of suicide compared to the general population.

Of the states that have imposed restrictive preferred drug lists and prior authorization requirements in their state Medicaid programs, most have recognized that these types of restrictive policies are inappropriate for beneficiaries with mental illnesses and elected to exempt such beneficiaries from restrictive preferred drug lists and prior authorization requirements.

Further, this alternative flexible formulary is consistent with the finding of President Bush's New Freedom Commission on Mental Health. In their Final Report from 2003, they noted that "efforts to strengthen or improve Medicare and Medicaid programs should offer beneficiaries options to effectively use the most up-to-date treatments and services."

Finally, in a recent report circulated to State Medicaid Agencies entitled "Psychiatric Medications: Addressing Costs without Restricting Access", CMS encourages state Medicaid directors to implement these same types of innovative alternatives instead of restrictive formularies and prior authorizations that increase the risk of the use of multiple prescriptions, reduced compliance, and poor outcomes. NAMI urges CMS follow this example and integrate the same strategies in the Medicare prescription drug benefit.

BILL FRIST

U.S. SENATE MAJORITY LEADER • TENNESSEE

FOR IMMEDIATE RELEASE
September 14, 2004

Bob Stevenson (202) 224-4445
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Nick Smith (202) 224-3355

Senate Finance Committee Hearing
"Implementing the Medicare Prescription Drug Benefit and Medicare Advantage Program: Perspectives on the Proposed Rules"
Statement by U.S. Senate Majority Leader Bill Frist, M.D.

Mr. Chairman, thank you for holding this hearing to focus on implementing the Medicare prescription drug benefit and Medicare Advantage program. Today, the Committee will hear from CMS Commissioner Mark McClellan and a number of other witnesses who will give us greater insight into the implications of the proposed regulations for these major aspects of the Medicare Modernization Act (MMA).

Mr. Chairman, I appreciate the seriousness and thoroughness with which you have led this committee in its responsibilities for overseeing the implementation of this landmark law. I know you share my goal of making sure that the MMA provides seniors with the relief they are entitled to and that Congress intended.

Dr. McClellan, Secretary Thompson, and their team at the Department of Health and Human Services have done a tremendous job in getting out proposed rules. They have been open and accessible to seniors, providers, and all interested parties as these rules are finalized and the Medicare prescription drug program is implemented.

I wish I could say that all members of Congress—whether they supported or opposed the Medicare law—were working toward the same goals as Dr. McClellan and Chairman Grassley. Unfortunately, however, some of my colleagues have spent more time and effort during the past few months trying to score political points rather than helping seniors get the relief they are entitled to under the law and the new prescription drug discount cards.

This is an election year. Yet, I have been surprised by the lengths to which some have gone to criticize and confuse. It's too bad, because the new Medicare law provides such meaningful benefits for seniors and Americans with disabilities.

Before President Bush signed the MMA into law last year, seniors were denied coverage under Medicare for prescription drugs—the most important tool in a physician's arsenal to prevent illness and fight disease. Beginning in 2006, all seniors will have the opportunity to get coverage. Already, over four million seniors are getting real savings and direct financial assistance through the prescription drug discount card.

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Before President Bush signed the MMA, Medicare did not cover the cost of a routine physical examination. Next year, it will begin covering baseline physicals for all seniors entering the program—as well as new preventive screenings for cardiovascular disease and diabetes.

Before the MMA, we had very little disease management and chronic care management for seniors. We did not link Medicare payments to quality. We did not provide incentives for doctors to use modern health information technology to prescribe drugs or order tests. Going forward, these will be part of the fabric of the traditional Medicare program.

Before President Bush signed the MMA, survey after survey showed that doctors were leaving the Medicare program or planning to cut back the services they provided to seniors because their practice expenses were climbing and they faced real cuts in Medicare reimbursement. Payments in rural America lagged far behind. The MMA changed all that.

Last week's announcement about Medicare premiums and deductibles for 2005 became yet another opportunity for a political attack against the new Medicare law, and the President. Some of those who led these new attacks were not being straight with the American people.

I'm sure we will have a more complete opportunity to discuss this and other issues today. I will have a few questions about the Part B premium, and other issues, where I hope we can set the record straight. I look forward to hearing from all our witnesses.

-30-

04-207

United States Senate

WASHINGTON, DC 20510

September 30, 2003

Dear Medicare Conferee:

We are writing to ask you, as a member of the Medicare conference committee, to ensure that the final Medicare bill includes a meaningful increase in Medicare+Choice funding in fiscal years 2004 and 2005. While the Senate bill makes a modest step toward this goal, we hope that the stronger provisions in the House bill will be preserved in conference.

For nearly 5 million Medicare beneficiaries across America, Medicare+Choice is an essential program that provides high quality, comprehensive, affordable health coverage. These seniors and disabled Americans have voluntarily chosen to receive their health coverage through Medicare HMOs and other private sector plans because of their excellent value. To preserve this important option for seniors across the country, bipartisan legislation was introduced in the Senate as S. 590, the "Medicare+Choice Equity and Access Act."

Co-sponsored by Senators Schumer and Santorum, S. 590 sought to increase reimbursement rates and add new reimbursement options for Medicare+Choice programs. Although the Senate version of the Medicare bill does include a modest increase in reimbursement rates in FY 2005, we were pleased to see that the House version contains a more comprehensive commitment to strengthening Medicare+Choice beginning in 2004.

Medicare+Choice uses private sector innovations to offer all of the traditional Medicare benefits in addition to extra benefits such as prescription drug coverage, vision benefits, and hearing aids. These added services are particularly important to low-income seniors who cannot afford the high out-of-pocket costs they would incur under the Medicare fee-for-service program. In many cases, this program is the only option for low-income seniors to receive comprehensive, affordable health coverage.

But in recent years, lack of adequate government funding for the Medicare+Choice program has steadily reduced the health plan choices and benefits of seniors across the nation. As funding increases have continually fallen short of rising health care costs, seniors have watched the quality of their health care decline. Each year, health plans deprived of essential funding have been forced to eliminate benefits, increase seniors' out-of-pocket costs, or even withdraw completely from certain areas.

We strongly support additional Medicare+Choice funding for two very important reasons: (1) to protect the health care choices and benefits of the nearly 5 million Medicare beneficiaries who are currently enrolled in private sector health plans; and (2) to strengthen the foundation for future health plan choices.

We believe that the Medicare+Choice funding provisions in H.R. 1 are critically important to preserving choice and quality for America's seniors. We urge you to include these provisions in the final bill reported out of the Medicare conference committee.

Sincerely,

Hillary Rodham Clinton

name manufacturer not to sell the generic drug.

Our legislation closes this loophole for those who want to cheat the public but keeps the system the same for companies engaged in true competition. I think it is important for Congress not to overreact and throw out the good with the bad. Most generic companies want to take advantage of this 180-day provision and deliver quality generic drugs at much lower cost for consumers. We should not eliminate the incentive for them. Instead, we should let the FTC and Justice look at every deal that could lead to abuse, so that only the deals that are consistent with the intent of that law will be allowed to stand. The Drug Competition Act accomplishes precisely that goal, and helps ensure effective and timely access to generic pharmaceuticals that can lower the cost of prescription drugs for seniors, for families, and for all of us.

The effects of this amendment will only benefit the effort to bring quality health care at lower costs to more of our citizens. The Drug Competition Act enjoyed the unqualified support of the Senate last year, and I am pleased that my colleagues have recognized that it fits well within the framework of the Prescription Drug and Medicare Improvement Act of 2003. It is a good complement to the larger bill and does nothing to disrupt the bill's balance. I sincerely hope that this commonsense legislation is a part of any final agreement with the House on the larger Medicare prescription drug bill.

(At the request of Mr. DASCHLE, the following statement was ordered to be printed in the RECORD.)

• Mr. KERRY. Mr. President, I wish to express my enthusiastic support for the amendment Senators SCHUMER and SANTORUM offered to increase funding for the Medicare+Choice Program in 2004 and 2005. This amendment addresses a critically important issue that has far-reaching implications affecting the health care benefits of millions of low-income and minority seniors. I am pleased to be a cosponsor of this amendment to ensure that this urgently needed funding increase is included in the Medicare bill.

I believe we must take bold action to address the fact that Congress has not provided adequate funding for the health care of Medicare beneficiaries who select HMOs and other private sector health plans. In many parts of Massachusetts, and in other parts of the country, funding for Medicare+Choice plans has been limited to annual increases of only 2 percent in most years since 1998. These increase are inadequate at a time when health care costs are rising by 8 to 10 percent annually. This level of inadequate funding is unfair to the 170,000 Medicare beneficiaries in Massachusetts who have selected private health plan options. I am a strong supporter of the wonderful health plans we have in Massachusetts—Harvard, Tufts, Blue Cross/Blue Shield, and Fallon Community Health Plan. We must step up to the plate to help these plans—nonprofit plans in my State—in their time of need.

The Schumer-Santorum-Kerry amendment takes important steps to address this problem. By providing funding now to stabilize existing private health plan options for Medicare beneficiaries, we can help ensure that the proposed Medicare Advantage Program will be successful in the future. Our amendment lays the groundwork for successful long-term efforts to provide beneficiaries with high-quality health care choices.

As the Senate continues to debate changes in Medicare, it is important for us to remember that, for more than 4.5 million Medicare beneficiaries across America, Medicare+Choice is an essential program that provides high-quality, comprehensive, affordable coverage that is not always available, or affordable under the Medicare fee-for-service program. These seniors and disabled Americans have voluntarily chosen to receive their health coverage through Medicare HMOs and other private sector plans because they recognize the value they offer.

Seniors in Massachusetts have come to rely on the high-quality health care they receive through their Medicare+Choice plans. Prescription drugs coverage, disease management services, physician exams, vision benefits, and hearing aids are examples of the additional benefits that are routinely offered by their Medicare+Choice plans.

These additional benefits are valued by all seniors, but they are particularly important to low-income seniors who cannot afford other Medicare supplementary plans that might provide them such benefits but at a greater cost.

As the Medicare debate moves forward, it is important for Congress to remember that Medicare+Choice serves as a vital safety net for many of our Nation's most vulnerable seniors. For millions of beneficiaries who cannot afford to purchase a Medigap policy, Medicare+Choice is their only hope for obtaining comprehensive health coverage.

The Schumer-Santorum-Kerry amendment focuses on protecting this important option for seniors who have nowhere else to turn for the quality health coverage they need. I urge my colleagues to support the additional funding that is urgently needed to strengthen the Medicare+Choice Program for seniors. This should be among our highest priorities in this year's Medicare debate.•

Mr. CARPER. Mr. President, when I ran for the U.S. Senate, I promised Delawareans that I would work in a bipartisan fashion to provide a Medicare prescription drug benefit for our Nation's seniors. I pledged that I would seek consensus around what is right with competing Republican and Democratic plans. Along with my Democratic colleagues, I would support voluntary coverage that is available and affordable for all seniors. Along with my Republican colleagues, I would support choice and competition to constrain costs. And to the extent we found ourselves constrained by limited resources, I would seek to provide the greatest assistance to those with the greatest needs.

The bill before us today achieves some of that vision. It is bipartisan. It will provide a benefit available to all seniors on a voluntary basis. It will harness market forces to strengthen the integrity of the Medicare Program for the future. And it will provide comprehensive health security to our most vulnerable, low-income seniors.

Still, the bill we have before us today is not everything I would have hoped for. The overriding priority of the current majority here in Congress has been to make dramatic reductions in Federal revenues without corresponding reductions in Federal spending. As a result, there is insufficient money in the budget under which we are currently operating to provide the kind of comprehensive coverage that all seniors—not just low-income seniors—truly deserve. This is an unfortunate choice of priorities, I think, but it is the choice that this President and this Congress have made.

Unfortunately, the consequences of the majority's misguided priorities are evident in this legislation. When Medicare was created, the idea was to provide seniors with health coverage that was similar to the coverage available to most working Americans through their employers. This is what seniors expect when we say that we are providing them with a Medicare prescription drug benefit. However, the majority has only set aside for this bill about half of what it would take, according to the Congressional Budget Office, to provide seniors a benefit comparable to standard employer-provided coverage. Thus, there is a very noticeable gap in this bill's coverage, reflective of a substantial hole in our Nation's budget.

When seniors reach $4,500 in prescription drug costs, the coverage in this bill gives out. It does not kick back in until total spending reaches $5,800. It is widely acknowledged that this makes no sense. It makes no sense from an insurance perspective. It certainly is not reflective of the standard either in private employer-provided coverage or in the coverage provided to those of us who are fortunate enough to serve as Members of Congress. Nobody likes this gap in coverage. Nobody, so far as I can tell, defends it. However, because the root of problem is the majority's failure to set aside sufficient resources for this program, efforts to deal with the problem have only created new and potentially more serious difficulties.

For example, the authors of this legislation have attempted to narrow the coverage gap by not allowing employer contributions to count towards the calculation of seniors' out-of-pocket

United States Senate
WASHINGTON, DC 20510

May 25, 2004

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
314G Hubert H. Humphrey Building
200 Independence Avenue S.W.
Washington, D.C. 20201

Dear Administrator McClellan:

As you know, the current Medicare Sustainable Growth Rate (SGR) formula for reimbursing physicians and other health care practitioners has generated negative updates every year since 2001. According to the Medicare Trustees, the formula will lead to cuts of five percent a year from 2006 through 2012. Actions by Congress have prevented reimbursement cuts in the years 2003 through 2005, but next year, Congress will once again confront the need to consider a more permanent "fix" in the formula.

We know you recognize the magnitude of this problem and are committed to working towards an appropriate solution. We would like to recommend policy adjustments the Administration could make that would lead to more accurate calculations of the targets used in physician reimbursement. While such fine-tuning will not eliminate all of the problems in the current SGR formula, it will help facilitate Congress' efforts to develop a more reliable reimbursement system.

The cost of physician-administered drugs continues to be included in the SGR, even though these drugs are not "physician services." Spending on physician-administered drugs is increasing far more rapidly than spending on physician and practitioner services, so having drug spending in the SGR continues to distort the calculation of actual spending. It makes sense to remove drug spending from the SGR formula, and we encourage you to do so.

Additionally, the Administration's current physician-reimbursement calculation does not adequately capture the full impact of changes in laws, regulations, and new screening benefits as required by the Medicare law. In addition, the impact of a number of the Administration's actions, such as CMS coverage decisions, is excluded entirely from the physician-reimbursement calculation even though those decisions may have just as great an impact on patient demand for services as a statutory change. Such changes need to be fully accounted for in the SGR calculation.

The task confronting the Congress in rectifying the SGR formula is formidable. Any actions the Administration can take to more accurately account for the realities of spending on physician/practitioner services under the SGR formula, both as to actual spending and target spending, will facilitate Congress' efforts and enhance patient access to high quality care. Thank you for your efforts toward this end.

Sincerely,

Tom Kyl
Blanche L. Lincoln
Bob Dole
Jack Reed
Jeff Sessions
Mark Pryor
Ben Nelson
Barbara A. Mikulski
Debbie Stabenow
E. Benjamin Nelson
Ted Kennedy
Ron Wyden
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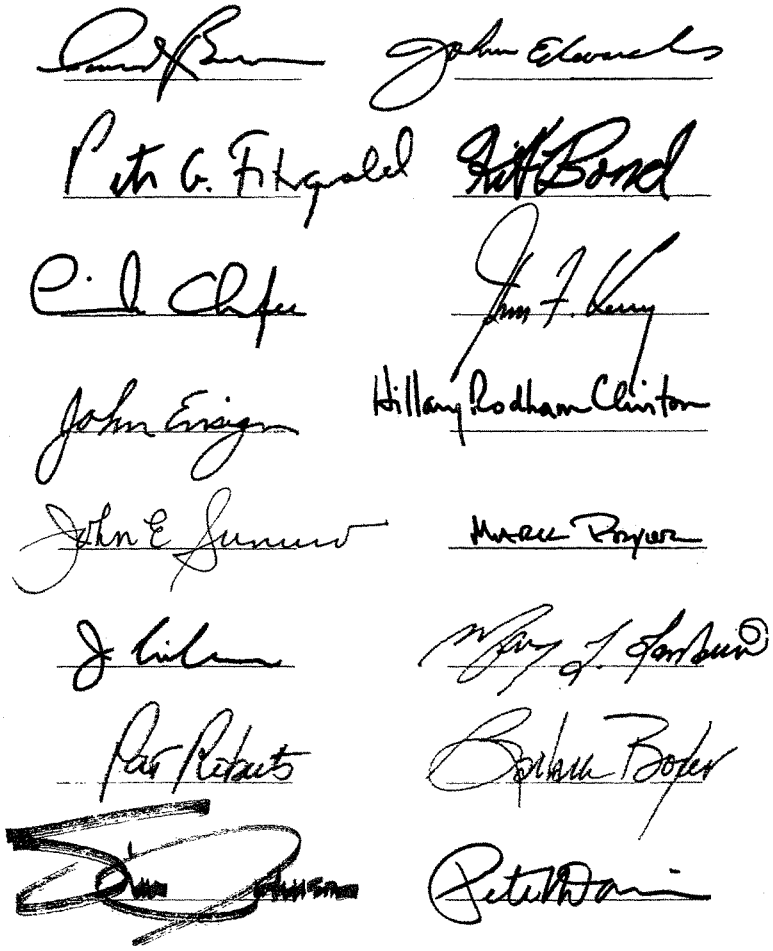

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70. Thad Cochran (R-MS)
71. Craig Thomas (R-WY)
72. Michael Enzi (R-WY)
73. Mike DeWine (R-OH)

U.S. SENATE COMMITTEE ON
Finance
SENATOR CHUCK GRASSLEY, OF IOWA - CHAIRMAN
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Opening Statement of Sen. Chuck Grassley
Hearing, "Implementing the Medicare Prescription Drug Benefit and Medicare Advantage Program: Perspectives on the Proposed Rules"
Tuesday, September 14, 2004

Today's hearing is on the proposed rules issued last month by the Centers for Medicare and Medicaid Services (CMS) to implement the prescription drug benefit and Medicare Advantage program established by the Medicare Modernization Act (MMA). Last year, members from both sides of the aisle devoted countless hours to make the prescription drug benefit and improved program a reality -- rather than wishful thinking -- for the forty million seniors and Americans with disabilities who depend on Medicare. After years of promising to get it done, last year we finally did it. For the first time, Medicare will offer a voluntary prescription drug benefit to all seniors in 2006. Beneficiaries also will have more coverage choices.

And if beneficiaries like the coverage they have, they can keep it. A number of beneficiaries told me that they are completely satisfied with their Medicare. They want to stay in fee-for-service Medicare, which is fine. In fact, Congress in the MMA took steps to make sure that beneficiaries across the nation have good access to physician services in fee-for-service. We had been hearing over the past few years that beneficiaries were finding it harder and harder to find a doctor who would see Medicare patients. The 4.5 percent physician payment cut that would have gone into effect next year would have made that situation worse. Both Republicans and Democrats worked to prevent the payment cut because if beneficiaries can't find a doctor, Medicare benefits would be meaningless.

We are here today because the Centers for Medicare and Medicaid Services have issued the proposed rules for implementing the new drug benefit and the expanded Medicare coverage options. These proposed rules bring the nation's Medicare beneficiaries an important step closer to having a much-needed, affordable prescription drug benefit and new coverage choices. Plain and simple, Medicare has crossed another milestone. Under the proposed rule, about one-third of all Medicare beneficiaries will be eligible for low-income assistance, meaning they'll have a drug benefit with no gap in coverage, and limited or no premiums, deductibles, or cost-sharing. For these beneficiaries, the drug benefit will cover as much as 85 to 98 percent of their drug costs.

Now one area that we will hear about today is the retiree drug subsidy. Employers provide coverage on a voluntary basis, and it is sorely evident that they are finding it harder and harder to do so. From 1991, long before the MMA's enactment, the number of large employers offering health coverage to their retirees dropped nearly 25 percent from 80 percent to 61 percent in 2003. The MMA sought to stem this alarming trend by providing $89 billion in direct subsidies and tax benefits

to protect retiree health coverage. This funding makes it more likely, not less likely, that employers will continue their retiree benefits. At the same time, I want to ensure that the direct subsidy and tax benefits provided are monitored closely. We must ensure that we maintain the utmost level of integrity in the implementation of this provision. Both the Department of Justice and the Department of Health and Human Services' Office of the Inspector General have expressed strong concerns with regard to this provision. Therefore, ensuring that only those employers who actually continue retiree health coverage receive the subsidy will be critical.

Another issue that I'm sure we'll hear about is the region size for the Medicare Advantage Regional Preferred Provider Organizations. PPOs are among the most popular coverage options for other Americans — about half of Americans with private insurance are enrolled in a PPO — but private plan options are not widely available to Medicare beneficiaries. Where private plans are available, they're very popular. Iowa beneficiaries who've joined a plan have told me that they like their plan. The Medicare Advantage Regional Plans will give beneficiaries more coverage choices by requiring plans to serve both urban and rural areas. Beneficiaries deserve choices between regular Medicare and other options that can offer them better coordinated care and additional benefits, such as 24-hour consulting nurse services. These services can be very valuable, particularly for beneficiaries with chronic conditions.

Congress also included numerous beneficiary protections in the new drug benefit. Rules and requirements about prescription drug formularies are among the most important protections because beneficiaries must be assured they can get coverage for the drugs they need. The United States Pharmacopeia has developed draft model guidelines for drug classes and categories to provide a framework for plan drug formularies. And CMS has additional oversight authority to make sure that plans do not use particular formulary designs to game the system by discouraging sicker people from enrolling. Again, I know that issues related to formulary design have engendered serious debate. And I'm looking forward to hearing our witnesses' perspectives on USP's draft guidelines and the proposed rules.

And by the way Dr. McClellan – I want to recognize you and your staff for your dedication and effort. CMS faced an enormous task in developing these proposed rules. You just took the helm at CMS a few months ago, and under your leadership, CMS has tackled this enourmous task with gusto and deserves credit for issuing the proposed rules in just under eight months after President Bush signed the MMA into law. That is an incredible accomplishment and you are your staff deserve our thanks for your dedication and hard work.

Now today, I am looking forward to an informative and insightful hearing. Of course, it is the political season and some may not be able to pass up the opportunity to take political pot-shots today. It is always much easier to tear something down, than it is to build something up. At the June drug card hearing, I quoted Bob Ball, former Commissioner of Social Security, who was involved in getting Medicare up and running. He said, "To a remarkable degree, opponents as well as supporters [of Medicare] tried hard to be helpful." Those words so relevant nearly 40 years ago are equally relevant today. I look forward to hearing from all our witnesses and to having a productive hearing.

Statement on

Implementing the Medicare Prescription Drug Benefit and Medicare Advantage Program: Perspectives on the Proposed Rules

by

Karen Ignagni
President and CEO
America's Health Insurance Plans

Before the
U.S. Senate Committee on Finance

September 14, 2004

Good morning, Mr. Chairman and members of the committee. I am Karen Ignagni, President and CEO of America's Health Insurance Plans (AHIP). I appreciate having this opportunity to testify on implementation of the Medicare Advantage program and the Medicare Part D prescription drug program.

Introduction

AHIP is the national trade association representing nearly 1,300 private sector companies providing health insurance coverage to more than 200 million Americans. Our members offer a broad range of health insurance products in the commercial marketplace and also have demonstrated a strong commitment to participation in public programs.

For more than 20 years, our member companies have been working to meet the health care needs of Medicare beneficiaries. Our broad-based membership includes Medicare Advantage organizations and Medicare cost contractors that cover almost 5 million beneficiaries and Medigap carriers that cover 10 million beneficiaries.

All segments of our membership, regardless of which products they offer, are committed to providing beneficiaries with affordable protection against high out-of-pocket health care costs. By covering more than the traditional Medicare program, our members serve as a crucial health care safety net for many minority beneficiaries with chronic diseases and for many low-income beneficiaries who cannot afford the high out-of-pocket costs they would incur under the traditional Medicare program.

Our member companies enthusiastically support the Medicare Modernization Act of 2003 (MMA), and we applaud Congress for enacting this historic legislation to improve choices and benefits for Medicare beneficiaries. As a direct result of this legislation, millions of beneficiaries already are receiving improved health coverage that AHIP's member companies are offering through the Medicare Advantage program and prescription drug assistance that our members are sponsoring through the Medicare-Endorsed Prescription Drug Discount Card Program. In

addition, beginning in 2006, our members will be offering local health plan options, new regional health plan options, a prescription drug benefit, and two new Medigap options.

Importance of Short-Term MMA Reforms

The MMA reforms scheduled for implementation in 2006 are closely linked to the stability of the current private sector Medicare program. Recognizing this reality, the MMA provided an immediate funding increase for Medicare Advantage, in both 2004 and 2005, to ensure that the existing locally-based program would remain in place as a solid platform for launching new components of the Medicare program in 2006. This was a critical step that Congress needed to take, first, to address the instability in the private sector Medicare program caused by the unintended consequences of the Balanced Budget Act of 1997 (BBA) and, second, to expand beneficiary choices through both local and regional plans in 2006 and beyond.

For the past five years, AHIP and our members have urged Congress to address the funding crisis in the private sector Medicare program. During most of these years, funding for the benefits of a significant majority of private health plan enrollees increased by only 2 percent annually, at a time when health care costs were increasing by 8 to 10 percent annually. Congress addressed this problem by providing funds to stabilize private health plan benefits and choices. This funding increase was included in the MMA largely because a core group of 130 Members of Congress – 81 Democrats and 49 Republicans – worked hard to build support for this priority. The Finance Committee deserves special credit for working to ensure that these funds were passed into law.

Just as Congress did its part to strengthen Medicare for seniors and individuals with disabilities, I am proud to report that our members have followed through by using the 2004 funding increase to expand benefits and reduce costs for the beneficiaries they serve. The Centers for Medicare and Medicaid Services (CMS) has reported that 95 percent of the additional funding is being used to help beneficiaries this year through reduced premiums and cost-sharing, increased benefits, and enhanced access to providers. The remaining five percent has been put in a reserve fund to stabilize benefits in 2005.

As a direct result of the MMA, 3.7 million beneficiaries – accounting for 80 percent of all Medicare Advantage enrollees – have received increased benefits through their Medicare Advantage plans since March 2004. In addition, premiums have been reduced for 1.9 million enrollees and co-payments have been reduced for 2 million enrollees in Medicare Advantage plans. Overall, premiums for all Medicare Advantage enrollees nationwide have declined by an average of 26 percent. These coverage improvements are clear evidence that the MMA is providing significant value for Medicare Advantage enrollees and, at the same time, has helped to stabilize the existing program as a foundation for implementing future reforms.

Since the enactment of the MMA, 22 Medicare Advantage organizations have expanded their service areas, thus providing new Medicare health plan choices for 9 million beneficiaries. CMS will announce additional expansions in the very near future. Yesterday, September 13, was the deadline by which Medicare Advantage organizations were required to notify CMS of their intention to participate in the program during the 2005 contract year and, additionally, submit proposed premiums and benefits for next year. In our ongoing discussions with our member companies, they have consistently expressed their interest in expanding their participation in the Medicare Advantage program. We are working to compile information on the expanded choices that will be available to Medicare Advantage enrollees in 2005. We hope to be able to share this information with the committee in our oral testimony.

MMA Reforms Scheduled for Implementation in 2006

Looking ahead to 2006, our member companies are strongly committed to the success of the improvements the MMA establishes for the Medicare program. Many of our members are now considering the opportunities for participation in the new Medicare program in 2006 – offering Medicare Advantage local and regional plans that include prescription drug benefits, offering prescription drug plans (PDPs), and offering the new Medigap benefit packages. Therefore, we are working diligently to provide feedback to CMS on a broad range of implementation issues.

We appreciate the agency's efforts to solicit input from health plans and other entities that are planning to continue their Medicare Advantage local plan participation and considering entering the new programs. CMS has dedicated significant resources to working with the private sector to ensure that expanded choices and benefits will be available to beneficiaries. Our member companies are also pleased that the agency is demonstrating a commitment to establishing a strong public-private partnership that will provide a foundation for implementation of the MMA reforms. CMS' efforts have included:

- a willingness to hear from stakeholders during development of the proposed regulations concerning practical issues and questions related to implementation of the MMA;

- public meetings to solicit comments on the implementation of Medicare Advantage and the Part D prescription drug benefit and on the USP draft model guidelines; and

- solicitation in the proposed regulations of comments from stakeholders on a broad spectrum of issues in an effort to make the final regulations workable and to support successful initial implementation of the program.

While we recognize that the implementation timeframes are challenging for both the government and the private sector, our members are focused on meeting these challenges and offering beneficiaries a wide range of choices. We are working with our member companies to develop detailed comments on all key aspects of the proposed rules and each of the specific programs they cover by October 4, which is the deadline CMS has established for submission of public comments. We would be delighted to provide the committee with our comments, and we would be pleased to provide any additional information or respond to any questions you may have.

As our members evaluate the proposed rules, we will be making comments that reflect our emphasis on three broad principles that may also be useful for the committee:

- Program Administration: We hope that our comments on the proposed rule will assist CMS in its goal to further establish a regulatory framework that adds value for beneficiaries and makes judicious use of CMS and private sector resources.

- Time Frames: We have asked CMS to provide guidance on key implementation issues as quickly as possible to allow the private sector to develop the operational capacity to participate in the new programs that will be implemented in 2006.

- Beneficiary Information: The wide dissemination of clear, user friendly, and balanced information about the new programs will be critical to the ability of beneficiaries to select the options that best meet their needs. We will be encouraging CMS to begin an effort to work with a broad spectrum of stakeholders in the planning and implementation of an outreach effort.

With these guiding principles, we have been working with our members to evaluate all of the specific issues imbedded in the regulations, to understand their administrative implications and to provide the best possible advice about how to implement their many parts. The following pages highlight a small but important sample of the dozens of administrative and regulatory issues associated with these MMA reforms. Our final comment letter to CMS will include more specifics on these issues and myriad technical recommendations.

USP Model Categories and Classes

We generally support the approach the U.S. Pharmacopeia (USP) has proposed for establishing model categories, classes, and subdivisions of prescription drugs that Prescription Drug Plan sponsors and Medicare Advantage organizations may use in developing their formularies and providing clinically appropriate, affordable drug benefits for Medicare beneficiaries. AHIP and our member companies were active participants in an advisory group that provided input to the USP's Model Guidelines Expert Committee regarding the development of these draft guidelines.

While we anticipate providing recommendations to improve the USP draft guidelines, we believe that the approach proposed by the USP provides a workable foundation for balancing the

important goals of providing coverage for the drugs needed to treat the conditions Medicare beneficiaries experience while making the drugs accessible by keeping coverage affordable. One way in which the USP draft guidelines promote access to these drugs is by proposing a framework that provides sufficient flexibility for private sector organizations to use proven strategies to encourage clinical best practices and keep Part D coverage affordable.

USP has proposed categories and classes of drugs to which CMS' proposed requirement for the coverage of two drugs in each category or class would apply and additional subdivisions that highlight drugs that should also be included in drug plan formularies, but for which the two drugs per category/class requirement would be inappropriate. This approach should allow drug plan Pharmacy and Therapeutics (P&T) Committees to make evidence-based decisions about the selection of drugs that will be included in formularies to meet beneficiary needs and establish clinical programs that promote the appropriate use of covered drugs. This approach also will preserve the opportunity for drug plans to obtain favorable pricing agreements through their negotiations with manufacturers. If the model were to include a significantly larger number of categories and classes, the effectiveness of all of these activities would be seriously undermined with the result that drugs could be less accessible for beneficiaries.

In addition, we believe it is important to evaluate the proposed USP model within the broader framework of CMS' standards for formulary review and approval.

Formulary and Benefit Design

We will be encouraging CMS to establish criteria for the review and approval of formularies and benefits that will allow Medicare Advantage plan and Prescription Drug Plan Pharmacy and Therapeutics (P&T) Committees to maximize the value of evidence-based research and other relevant data in designing formularies and to establish related clinical guidelines and other programs to promote appropriate use of formulary drugs and quality care. These private sector tools and techniques help to integrate prescription drug benefits into comprehensive health coverage and, in the process, improve the quality and affordability of health care for Medicare beneficiaries.

From a beneficiary perspective, it also will be important to make full use of the flexibility available under the statute for the design of qualified prescription drug benefits to maximize this coverage. To this end, we support immediate implementation, on January 1, 2006, of the reinsurance demonstration that was authorized by the MMA to increase opportunities to offer coverage to fill the "donut hole" in the Part D benefit. We are in discussions with CMS about options for the design of the demonstration.

Designation of Regions

We have worked intensively with our members to develop a recommendation concerning the number of regions that should be established to fulfill the goal of maximizing the availability of Medicare Advantage regional plans to beneficiaries.

Our members strongly support Congress' objective of providing private sector options to beneficiaries in rural as well as urban areas. In response to CMS' request for comments on this topic in July, we reflected the view of many of our members that it would be prudent to begin with 50 regions, because under the challenging time frames of the MMA, building on current state-based licensure and provider networks will make broader plan participation possible in the near term. At the same time, we have indicated to the agency that we also have some members who prefer fewer regions and are looking carefully at the operational issues that would be involved in serving beneficiaries in multiple states.

In addition, as our members have been considering the question of how many regions should be established for the Part D prescription drug program, our July comments reflected the support of many of our members for 50 PDP regions in order to reduce the uncertainties inherent in the new program and provide opportunities for more sponsors to offer choices for beneficiaries. However, for this program, as well, we have members who are interested in serving multi-state regions.

All of our members are continuing to work through the many administrative issues involved in both of these areas.

Network Access Standards

Throughout the 2003 Medicare debate, our members offered a range of solutions for removing obstacles to health plan participation in areas where plans face serious challenges in reaching economically viable agreements with health care providers. We identified this issue as one of the most significant barriers to bringing Medicare Advantage options to rural areas. The MMA partially addressed this concern by providing modest additional funding for essential hospitals, which AHIP supported, in the event that negotiations conducted by Medicare Advantage regional plans are unsuccessful. This also remains a serious issue for Medicare Advantage local plans.

We will be supporting provisions of the proposed rules that would allow flexibility in the application of network adequacy standards. This flexibility is important, because in a number of rural and urban areas in the country, providers have been unwilling to contract with Medicare managed care plans, even at Medicare fee-for-service rates. This is particularly true in areas where provider competition is limited or nonexistent. Where these contracting problems occur, the regulations provide alternatives that continue to ensure enrollee access to covered services. We hope that these alternatives for meeting network adequacy standards under the Medicare Advantage program can be available to both local and regional plans to ensure that beneficiaries have broad access to the choices that are envisioned under the statute.

Coverage for Dual Eligibles

Meeting the special needs of beneficiaries who are dually eligible under the Medicare and Medicaid programs will be an important priority under the Medicare Advantage and Part D prescription drug programs in 2006 and beyond. We will be making two broad recommendations in this critical area.

First, the MMA contains authority for the establishment of special needs plans that exclusively or predominantly serve dually eligible beneficiaries and those with other special health care needs. To take full advantage of the opportunity to establish plans that focus on the unique needs of these beneficiaries, we believe that CMS should provide flexibility for private organizations to make proposals to CMS regarding the special populations that may be served (e.g., the frail

elderly) and the ways in which program administration should be tailored to facilitate the offering of special needs Medicare Advantage plans.

Second, in transitioning fully dual eligibles from Medicaid coverage of their prescription drugs to coverage under Part D, these beneficiaries will have an opportunity to select a drug plan. If they do not do so, they will be assigned to plans through a default enrollment process, subject to their ability to subsequently change plans if they choose to do so. We support an intensive outreach and information initiative to provide beneficiaries with user-friendly information to help them maintain continuity of care by staying in their current health plans with their existing physicians and other health care providers.

Systems Infrastructure for Coordination of Benefits

We will be supporting CMS' initiative to create a systems capability that will allow for the submission and accessibility of data that Medicare Advantage organizations and Prescription Drug Plan sponsors will need to administer the drug benefit for beneficiaries and that CMS will need to implement reinsurance and risk sharing provisions of the MMA. This capability is critically important to the goal of ensuring that beneficiaries are protected against catastrophic prescription drug costs. It is essential for this infrastructure to be in place on January 1, 2006.

Medigap

I also want to highlight our recommendations on two MMA issues that have significant implications for Medigap carriers and their policyholders. First, our members are concerned about changes that CMS has proposed to the standardized notice that the National Association of Insurance Commissioners (NAIC) has developed for informing Medigap policyholders about their options for prescription drug coverage. We have supported the notice that has been developed by the NAIC and will be providing detailed comments regarding the issues raised by the CMS draft. We are pleased that the NAIC's process for developing the notice has provided an opportunity for input from a broad range of interested parties, including our member companies. We are committed to working with the NAIC and CMS to develop a standardized notice that will enable beneficiaries to make thoughtful, informed decisions when choosing

between new and existing Medigap options, as well as the new Medicare Part D prescription drug plans.

Disclosure Requirements for Creditable Coverage

We also will be urging CMS to minimize administrative burdens as it works to implement the MMA's disclosure requirements for creditable prescription drug coverage. The MMA requires certain entities to disclose whether prescription drug coverage they offer or provide to Medicare beneficiaries is "creditable coverage" under the new Medicare Part D prescription drug benefit. This requirement, which applies broadly to insurers in the group and individual markets, should be implemented with two key goals in mind: (1) providing clear, accurate information to beneficiaries; and (2) limiting administrative burdens for the private sector.

Employer/Group Union Issues

We also have several recommendations to facilitate the offering of retiree drug coverage through Medicare Advantage and Prescription Drug Plans. A key issue for employers and unions and their retirees is the MMA subsidy for retiree drug benefits, which will be available to employers that offer drug coverage that meets a test, established by CMS, of actuarial equivalency to the standard Part D benefit. We believe this actuarial equivalency test should strike an appropriate balance between two important priorities: (1) allowing employers to qualify without being subjected to overly burdensome or complex requirements; and (2) avoiding potential windfalls to employers so that retirees will be helped by the subsidy and will not be disadvantaged. Also, we urge CMS to ensure that the subsidy program's data collection and reporting requirements for employers and unions are reasonable and that a payment process is established that will permit employers and unions to receive their payments in a timely fashion.

Additionally, to accommodate employers and union trust funds with retirees in multiple states, we support the implementation of a waiver for a national offering for the employer market. We commend CMS for indicating its willingness to follow the waiver structure established under the Medicare+Choice program. We support CMS' view that waivers, once approved, should generally apply to any plan offering that meets the waiver criteria. We also support CMS' view that waivers should allow maximum flexibility so that plans may determine which program

requirements need to be waived in order to structure benefits according to the needs of a particular employer plan.

Beneficiaries Are Well-Served by Private Sector Participation in Medicare

We are proud of the success our member companies have demonstrated in meeting the health care needs of Medicare beneficiaries. The private sector has a strong track record of providing high value under the Medicare program.

When the new Medicare options are launched in 2006, our members will continue to use private sector pharmacy benefit management tools and techniques to reduce out-of-pocket costs for beneficiaries and to improve quality by reducing medication errors. These tools and techniques include:

- programs that encourage the use of generic drugs;
- step therapy programs that promote proven drug therapies before moving to newer, different treatments that are not necessarily better;
- negotiated discounts with pharmacies that participate in a plan's network;
- disease management techniques that include practice guidelines to encourage the use of the most appropriate medications; and
- appropriate use of mail-service pharmacies.

Although government programs do not always use all of these techniques, a number of studies have demonstrated that the use of these techniques by private sector health plans is beneficial to enrollees in public programs. For example, a 2003 study, conducted by Associates and Wilson on behalf of AHIP, found that the PACE program in Pennsylvania – the largest state pharmacy

assistance program in the nation – could save up to 40 percent by adopting the full range of private sector pharmacy benefit management techniques.

Another 2003 study – conducted by the Lewin Group for the Center for Health Care Strategies – found that Medicaid managed care plans reduced prescription drug costs by 15 percent below the level states would otherwise have experienced under Medicaid fee-for-service programs. Health plans achieved these savings by performing drug utilization review, establishing pharmacy networks, and encouraging patients to take the most appropriate medications.

In addition, the Government Accountability Office (GAO) has reported that pharmacy benefit management techniques used by health plans in the Federal Employees Health Benefits Program (FEHBP) resulted in savings of 18 percent for brand-name drugs and 47 percent for generic drugs, compared to the average cash price customers would pay at retail pharmacies.

These findings demonstrate that the private sector is well-positioned to use its experience and capabilities to make prescription drugs more affordable for a broader range of Medicare beneficiaries.

In addition to improving access to safe, affordable prescription drugs, our members have longstanding experience providing comprehensive health coverage to Medicare beneficiaries. Let me briefly review several examples of how beneficiaries are well-served by our members' innovative practices in the Medicare Advantage program.

Private sector plans have applied the concept of disease management programs to their Medicare Advantage plans to improve quality of care for beneficiaries with chronic conditions by focusing on the comprehensive care of patients over time, rather than individual episodes of care. These programs provide specialized care to beneficiaries who have diabetes, congestive heart failure, end-stage renal disease, depression, cancer, and other medical conditions that commonly afflict the elderly. Currently, disease management programs are available to only a small number of Medicare fee-for-service enrollees under demonstration initiatives.

Private sector health plans and insurers also play an important role in providing health coverage to beneficiaries who are financially vulnerable. For many beneficiaries who are not eligible for retiree health benefits or Medicaid, the Medicare Advantage program serves as a health care safety net by providing comprehensive, affordable coverage that is not available under the Medicare fee-for-service program. Studies show that low-income and minority beneficiaries are more likely to enroll in Medicare Advantage plans than other beneficiaries.

The private sector also helps to keep out-of-pocket costs low for beneficiaries. A Rand study published in May 2003 found that Medicare health plans, when compared to the Medicare fee-for-service program, reduced out-of-pocket health care costs by $809 annually for the average beneficiary and by $2,160 annually for beneficiaries with the highest health care costs.

Enhanced benefits are another advantage of private sector participation in Medicare. CMS recently reported that 80 percent of all Medicare Advantage enrollees receive some form of prescription drug coverage in 2004. This is true even though government payments to plans do not yet include funding for prescription drugs.

These facts clearly demonstrate that beneficiaries are well-served by private sector participation in Medicare. With respect to both the quality and affordability of health care, the private sector has a strong track record that bodes well for its long-term role in the Medicare program.

Conclusion

Once again, we would like to commend CMS for its strong commitment to advancing a stable public-private partnership to ensure that beneficiaries receive prescription drug benefits that are affordable, effective, and accessible.

I also would like to reemphasize that our testimony today highlights only a sample of the many important issues that will impact the future success of the MMA reforms. When we submit our comments to CMS in early October, we will address the full range of implementation issues and

we will provide comprehensive and detailed comments that reflect our members' best recommendations on how to administer the programs in a way that meets beneficiaries' needs.

We appreciate the opportunity to testify today and will be delighted to share our detailed comments with the committee as soon as we submit them to the agency.

AHIP Responses to Questions from Committee Members
Senate Finance Committee Hearing
September 15, 2004

Questions from Senator Grassley –

Formularies

1. "Do you have a sense – for the average plan – how many times a year it changes its formulary and the types of changes it makes. For example, do plans generally add drugs mid-year versus drop drugs?"

Response:
Formulary decisions are based on recommendations of a Pharmacy & Therapeutics (P&T) committee. P&T committees generally include representation from various physician specialties (including general practitioners), pharmacists, and sometimes other health care professionals. P&T committees develop and update the drug formulary, and manage and administer the formulary process. P&T committee members review medical journals and other clinical literature, including clinical trial results, in making their formulary status decisions.

Most P&T committees meet at least quarterly -- some meet every other month, and a few may meet monthly. Throughout the year, P&T committee members review recent new drug approvals by the Food and Drug Administration (FDA), new FDA-approved uses for current drugs, new dosage forms of existing drugs, and may recommend changes to the formulary based upon their evaluation of new information. Health plans also respond to safety concerns that may arise and change their formularies accordingly. This allows the health plan to base its formulary decisions on the most current available information.

2. "If it drops a drug, is it more likely one that isn't commonly used? What I'm trying to get at is how much stability is there in plan's current formularies – particularly for drugs commonly used by seniors?"

Response:
Decisions to drop a drug from the formulary are not made lightly. Changes in a drug's formulary status generally occur because new studies or other reliable information indicate the product has no therapeutic advantage over similar drugs, is more costly than therapeutically equivalent drugs, has recently raised safety concerns, and/or can be replaced with a better – sometimes more costly – therapeutic alternative. Health plans and PBMs have an incentive to minimize formulary changes, in part, because of the costs they incur in communicating such changes to physicians, pharmacists, and plan participants.

Many health plans offer a transition or "grandfather" period to allow continued coverage for a drug that may have changed formulary status when safety is not the reason for the status change. This allows the plan/PBM to inform the patient and the physician about the

formulary status change and to work with the physician and the patient to switch the medication to a clinically appropriate alternative on the formulary. In addition, plans generally have a process in place that provides the beneficiary access to a non-formulary or non-preferred product. Health plans that operate closed formularies make non-formulary drugs available based upon a determination by the prescribing physician that the product is medically necessary. Health plans offering tiered formularies allow beneficiaries access to non-preferred products if they agree to pay higher copayments or coinsurance. These mechanisms ensure beneficiaries have access to the medications they need while plans use proven tools and techniques to make prescription drug coverage more affordable.

Medicare Advantage

1. "When we were drafting Title I and Title II of the new law, we heard about the challenges of setting up adequate networks in rural areas. Many health plans were concerned that hospitals in rural areas would demand exorbitant reimbursements because of the lack of competition in rural areas."

   Response:
   Health plans often face difficult negotiations with hospitals that are the sole providers available for many miles, and, may therefore, have little economic incentive to negotiate a contract. However, this is not always a rural problem as has been established by the Federal Trade Commission (FTC) and Department of Justice (DoJ). For example, the *New York Times* has reported that hospitals that have gained market power through consolidation have demanded rate increases as high as 40 to 60 percent. The report issued by the FTC and DoJ in July 2004, entitled "Improving Health Care: A Dose of Competition," provides helpful analysis in this area.

2. "I would ask you to comment on how negotiations work among health plans and hospitals in rural areas. What kind of concessions could a plan have to make when negotiating with a local hospital, when that hospital may be the only facility for many miles to service an enrollee?"

   Response:
   There are fundamental similarities between the marketplace dynamics in rural areas where a hospital is often the sole community provider and in areas where consolidations have taken place. In both situations, hospitals may demand high rate increases as noted above. In 2003, the FTC heard testimony from several health plan executives who explained several other possible consequences when hospitals acquire considerable market power. In some markets, for example, hospital systems have demanded that health plans contract with every facility affiliated with their system – even if some facilities filled no real need in the health plan's network or did not offer services at competitive rates. In addition, market dominant facilities may pursue a strategy of "terminate then negotiate" in which a provider ends a contractual relationship with a health plan – threatening the dislocation of health plan enrollees – before beginning meaningful negotiations with the health plan.

Establishing networks in areas where providers have significant market power has been a considerable barrier to expanding private plan participation, both in rural areas and in other areas where these conditions exist. AHIP supports innovative solutions to these problems, both for Medicare Advantage regional and Medicare Advantage local plans, to expand private health plan choices for beneficiaries.

3. "How do you think a regional Medicare Advantage plan could demonstrate that the plan made a 'good faith effort' to contract with an essential hospital?"

   Response:
   The MMA establishes a mechanism for supplemental payments to essential hospitals in the event that an MA regional plan certifies that it has not been possible, despite good faith efforts, to negotiate contract terms. Although funding for this provision is limited, AHIP supports implementation of this authority to assist MA regional plans in meeting network adequacy requirements. As we discuss in our comments to CMS' proposed rules for the Medicare Advantage program, local plans also experience significant challenges in reaching viable agreements with providers in some geographic areas and could also benefit from this provision.

   We anticipate that CMS will issue guidance regarding the information that MA regional plans will be required to provide to demonstrate that "good faith" negotiation has taken place, so that a hospital would be eligible for additional payments. We believe that CMS will be able to establish requirements that ensure appropriate accountability, but are flexible enough to take into account the inevitable variation in the course of negotiations.

4. "Do you think that the Centers for Medicare and Medicaid Services have enough authority and resources to implement this section of the new law?"

   Response:
   AHIP believes that CMS has sufficient statutory authority to implement the Medicare Advantage and Medicare prescription drug benefit provisions of MMA. AHIP has been encouraged by recent efforts by CMS leadership to hire a number of experts with relevant expertise in order to improve their ability to implement provisions in the MMA. For example, CMS has hired experts in employer group benefits and pharmacy benefit management. As of September, 2004, the agency had increased staffing for the 1-800-MEDICARE hotline to 3,000 FTEs in order to provide additional customer service to Medicare beneficiaries. CMS is continually improving its services and resources to meet the wide needs of all parts of the Medicare program. We anticipate that the agency will continue to take constructive steps necessary to implement all aspects of MMA.

Question from Senator Baucus

1. "Ms. Ignagni, at the hearing, I asked Dr. McClellan about risk adjustment. My strong preference is for risk adjustment to be applied across the entire program rather than just across private health plans. Does AHIP have a position on the application of risk adjustment? Does the answer change when you take into account the calculation that the benchmark will be 107-108% of fee-for-service when competitive bidding starts in 2006?"

Response:
The Balanced Budget Act of 1997 (BBA) established the Medicare+Choice program, now Medicare Advantage, and changed the way health plans were paid. The BBA established that payments to plans shall "provide for implementation of a risk adjustment methodology that accounts for variations in per capita costs based on health status and other demographic factors." CMS is currently phasing in the implementation of the HCC risk adjustment methodology which is applied to 30 percent of plan payments (which increases to 50% in 2005, 75% in 2006, and 100% in 2007). The remaining portion of plan payment is adjusted based on demographic characteristics.

AHIP has always affirmed that Medicare payments to health plans should be accurate and that they should fairly reflect the health care service needs of the Medicare beneficiaries who enroll. In the conference report to the Balanced Budget Refinement Act of 1999, Congress stated that the transition to 100% health status-based risk adjustment should be made on a budget neutral basis. Congress therefore clearly intended that overall Medicare Advantage payments should not be adversely affected because of the implementation of the health status-based risk adjustment model. There is no change in the Congressional intent as laid out in the MMA and we support the continued enforcement of a budget neutral risk adjuster.

We disagree with the assertion that Medicare Advantage plans are paid approximately 107 percent of what it would cost to cover their enrollees in the Medicare fee-for-service (FFS) program. This figure is incorrect, because the methodology used to arrive at this amount does not account for the full effect of graduate medical education (GME) payments which Medicare makes directly to teaching hospitals. Further, this analysis incorrectly assumes that hospitals reduce their contracted rates with health plans to account for GME payments made by Medicare. These realities should be taken into account when comparing Medicare Advantage payments and FFS payments -- GME payments made by the Medicare program on behalf of beneficiaries are a cost to Medicare and should be included in the estimate of FFS costs. The flawed analysis underlying the 107% calculation also underestimates FFS costs because it does not include the costs associated with providing care that Medicare beneficiaries may have received at facilities operated by the Department of Veterans Affairs (VA) and the Department of Defense (DoD). To achieve an accurate comparison of Medicare Advantage and Medicare FFS payments, GME and VA/DoD costs should be included in the equation.

Question from Senator Rockefeller

1. "As you are aware, the Medicare Modernization Act calls for 10-50 regions to be established for the Medicare Advantage (MA) regional PPO program. I understand that ensuring seniors in rural states -- such as West Virginia – have adequate access to coverage options may require that we be combined with another state or states that offer a more attractive insurance market in order to appeal to carriers who otherwise may not be compelled to do business here. I am concerned, however, that placing West Virginia in a very large region encompassing too many states would also serve to limit the options available to our Medicare beneficiaries because small to mid-size plans that are locally trusted and otherwise fully capable of delivering benefits could effectively be excluded from participation. Is this a valid concern?"

   Response:
   We believe that regions should be selected with the goal of maximizing the availability of Medicare Advantage regional plans to beneficiaries. Our members strongly support Congress' objective of providing private sector options to beneficiaries in rural as well as urban areas. In response to CMS' request for comments on this topic in July, we reflected the view of many of our members that it would be prudent to begin with 50 regions, because under the challenging time frames of the MMA, building on current state-based licensure and provider networks will make broader plan participation possible in the near term. At the same time, we have indicated to the agency that we also have some members who prefer fewer regions and are looking carefully at the operational issues that would be involved in serving beneficiaries in multiple states.

TESTIMONY OF
MARK McCLELLAN, MD, Ph.D.
ADMINISTRATOR
CENTERS FOR MEDICARE & MEDICAID SERVICES
ON
TITLES I AND II: FEATURES OF THE PROPOSED REGULATIONS
BEFORE THE
SENATE COMMITTEE ON FINANCE

September 14, 2004

Chairman Grassley, Senator Baucus, distinguished members of the Committee, thank you for inviting me here today to discuss the most dramatic and innovative modifications to the Medicare program since its inception in 1965. I want to thank the Committee members for your interest in the Medicare program, your hard work on the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), and your support of the Centers for Medicare & Medicaid Services (CMS) as we work to implement this important new law.

The two regulations we are here to discuss today lay out CMS' proposal for delivering new services and benefits created by this Congress and the Administration in the MMA. This new law provides better benefits -- including prescription drug savings of more than 50 percent for the average senior without coverage -- and improved access to health care services through Medicare. These proposed regulations create a new voluntary prescription drug benefit under Medicare, as well as new health plan choices, improved health care for rural America and improved preventive care benefits.

The new prescription drug benefit will allow all Medicare beneficiaries to enroll in drug coverage through a prescription drug plan or Medicare health plan with Medicare paying, on

average, for 75 percent of the premium for standard Medicare drug coverage. Additional benefits for Medicare beneficiaries who have limited means will cover, on average, approximately 95 percent of their drug costs. The new benefits will also provide support for employers or unions that provide their retirees with drug coverage making it possible for those sponsoring institutions to provide more help to the retirees. All the new Medicare benefits are voluntary, as seniors can choose to keep their existing traditional coverage. With these regulations we are delivering on our promise to America's seniors to provide better benefits, leading to better health and real savings on their out-of-pocket medical costs, including prescription drugs.

The MMA is a substantial piece of legislation, containing 227 provisions requiring implementation by the end of 2004 alone. As shown in the attached charts, CMS has implemented 149 of those provisions, or 66 percent, and is currently in the process of finishing the remaining 78. I might also point out that of those due by August 30, 2004, CMS has implemented 91 percent, with the remaining handful in progress. Just for example, CMS published the regulation setting up the Medicare approved drug discount card on December 15, 2003, just seven days after President Bush signed the MMA into law. CMS is well on its way to full and timely implementation of this important legislation.

Background

Overall, Medicare has clearly been a success in providing needed care to America's seniors and disabled, but it has not kept pace with modern health care in its lack of coverage of most outpatient drugs and in failing to provide access to coordinated-care options that reduce costs.

At Medicare's inception in 1965, the use of drugs to treat disease was not nearly as prevalent as it is today. As a result, despite assistance offered through State Medicaid programs, Medigap plans, employer retiree plans and other insurers, approximately one-quarter of Medicare beneficiaries lack basic prescription drug coverage. The lack of prescription drug coverage is a particular problem for beneficiaries with limited financial means, and those with catastrophic drug costs, situations that force difficult choices. Under the MMA, all of these beneficiaries have the option of new, subsidized, voluntary drug coverage, as well as new support to keep their current retiree coverage secure.

In addition to the standard drug benefit, which is available to all beneficiaries, the MMA and the proposed regulations provide several approaches for beneficiaries to get even more comprehensive coverage. For example, low-income seniors and people with a disability who have limited means – about a third of all people with Medicare – will get access to comprehensive coverage, with no or limited premiums, deductibles, co-payments or coinsurance, and no gaps in coverage. Medicare beneficiaries with retiree coverage may benefit from a set of options to get affordable, enhanced coverage, including a new retiree drug subsidy as well as options for employers and unions to wrap around Medicare coverage or offer Medicare-subsidized drug coverage themselves. Beneficiaries who are contributing to their own coverage, through an employer's retiree plan, for example, may be able to use the new Medicare subsidies to obtain enhanced coverage at a lower cost.

The new Medicare law and the proposed rules also allow states the flexibility to "wrap around" the comprehensive coverage for certain low-income beneficiaries in addition to providing net

savings to states by providing comprehensive coverage for "dual-eligible" beneficiaries (those eligible for both Medicare and Medicaid) and providing new subsidies for state retiree coverage. In addition, state pharmacy assistance programs, other individuals, and charitable organizations can contribute toward a beneficiary's out-of-pocket costs and still have those contributions count toward catastrophic coverage.

Finally, through the new Medicare Advantage (MA) program, beneficiaries will have access to a variety of modern integrated health insurance plans, including preferred provider organizations (PPOs). PPOs are the most popular health plans for younger Americans who are covered by commercial health insurance plans, but until now have not been prevalent in Medicare, particularly in rural areas.

The Regulations

The focus of today's hearing is the two proposed regulations published by CMS on August 3, 2004, which contain the Agency's recommendations for implementing Titles I and II of the MMA. These proposals take many important steps forward toward implementing the new law, and we are very anxious to "get it right," so that Medicare beneficiaries can get the maximum help from all the new benefits and choices made available through MMA. Consequently, we have also asked for comment on a number of options for implementing the law, and we are conducting a major public outreach effort to make sure we are hearing from all perspectives.

One of the primary goals of the regulatory process is to invite the public to work with the Federal government in formulating a means to best implement the law as passed by Congress. We

consulted widely with the private sector and other government entities during the development of these rules, and now, to educate ourselves as thoroughly as possible prior to finalizing the rule, we are soliciting public comments on all aspects of the proposals.

These two rules contain a number of instances where the Agency has specifically petitioned the public to assist in deciding which course to take when there are multiple objectives and goals that we want to achieve simultaneously. We are obtaining extensive public comment from experts in the fields covered by these rules and will use their comments to shape the final regulations, which are on schedule to be published in January 2005, so that the programs can go into effect in 2006.

Since announcing the regulations on July 26, CMS has been actively engaged in soliciting public input. We have held some twenty open door forums to educate the public and obtain feedback. These national conference calls are announced through our website and e-mail alerts, typically have background materials associated with them, and are geared toward specific concerns with the Medicare and Medicaid programs. Literally thousands of people from the private sector and other outside groups have participated in these calls and have provided CMS with the opportunity to explain and receive feedback on these two proposals.

CMS central office and regional office staff have also held numerous outreach and town hall meetings to both explain and solicit comment on various aspects of our work to implement the MMA. In addition to the open door forums and outreach events, Secretary Thompson and I have

personally been very active in meeting with Congressional and outside groups to hear their concerns and suggestions, and to explain our proposals.

The Drug Benefit

Under the new Medicare drug benefit, all Medicare beneficiaries will have access to a voluntary drug benefit. A typical beneficiary without drug coverage today, who is not eligible for low-income benefits, could see their total spending on drugs drop by 53 percent, or nearly $1,300. The savings for the standard drug benefit come from two main sources. First, beneficiaries who enroll in a Medicare drug plan, regardless of whether they qualify for low-income assistance or not, will pay lower prices for the drugs they purchase because the drug plans will be negotiating discounted prices with drug manufacturers. Prescription drug plans (PDP) and Medicare Advantage plans offering prescription drug coverage (MA-PD), will face strong pressures to keep drug costs low and pass those savings on to their enrollees. This negotiation is expected to reduce drug prices for beneficiaries by 15 percent initially, rising to 23 percent within 5 years. Even beneficiaries who have drug coverage aside from that offered through a Medicare drug plan can avail themselves of these lower prices by purchasing through the Medicare plan. These cost savings are expected to result from strong competitive pressures, including transparency in drug price and benefit information, for drug plans to negotiate discounted prices and manage drug costs to obtain the lowest costs possible while providing the drugs that beneficiaries need, and to pass these savings on to beneficiaries.

The proposed rule outlines an approach similar to the one used by the Federal Employees Health Benefits Program and other large health care payers. This approach is expected to provide the

best discounts on drugs – discounts as good as, or better than, could be achieved through direct government negotiation, resulting in prices that will be substantially better than Medicare's prior experience with price regulation for the drugs that it currently covers under Medicare Part B. We have seen such competition yield beneficial results in drug prices already, in the Medicare prescription drug discount card program, where numerous independent studies have found that prices are substantially lower on very broad drug formularies, as purchasing power combined with competitive pressures and public release of drug prices have driven prices down. Further, these price reductions are on the drugs that beneficiaries commonly use, including many drugs not included in the formularies of government-run drug plans. We expect prices under the drug benefit to be reduced even further from those available under the Medicare approved drug discount card program. With effective price negotiation and other tools to lower costs on the drugs that beneficiaries want, no Medicare beneficiary ever needs to pay anything close to list prices again.

The second way that the drug benefit will offer savings to Medicare beneficiaries is through the Federal government's subsidization of their monthly premiums and catastrophic costs. Medicare's approximately 75 percent subsidy, on average, for the standard drug coverage is expected to result in a beneficiary premium for this coverage costing about $35 a month in 2006. That is, for the first time, Medicare will be paying about $105 a month, per beneficiary toward the cost of drug coverage for all beneficiaries. (As noted above, low-income beneficiaries get even greater help.) In this subsidized coverage, in 2006, beneficiaries enrolling in the standard benefit will pay an annual deductible of $250, plus 25 percent of drug costs, up to an initial coverage limit of $2,250. After that point, once the beneficiary reaches $3,600 in out-of-pocket

spending, the Federal government and plans will pay about 95 percent of the beneficiary's drug costs. There will be no annual plan maximum, and coverage will never run out. Congress designed the drug benefit so that the number of beneficiaries who will have to fill in the gap between the initial coverage and the catastrophic coverage would be minimized. CMS estimates that more than two thirds of Medicare beneficiaries will not have to pay any money toward filling that gap. It is important to note, as well, that drug plans are required to pass on negotiated prices to the beneficiaries on all drug purchases. As a result, even when beneficiaries are responsible for the full cost of the drugs they purchase, the negotiated discounts mean that prices for those drugs will be lower than they would if the beneficiary did not belong to a plan.

The subsidy Medicare provides for standard drug coverage can be combined with other sources of assistance to provide even greater coverage. State pharmacy assistance programs, charitable organizations, and other individuals can contribute to beneficiary out-of-pocket costs and have those contributions count as "true" out-of-pocket expenditures when it comes to calculating how close the beneficiary is to reaching the $3,600 in out-of-pocket spending required to trigger catastrophic coverage. Beneficiaries, employers, and others can also use some of their existing contributions to buy supplemental or "high-option" coverage to enhance the standard coverage, while still obtaining substantial overall savings compared to what they or their employer are paying now because of the new Medicare subsidies.

Beneficiary Protections

The MMA incorporates substantial beneficiary protections from traditional Medicare and from the Medicare+Choice program. It also creates new rights and protections that are specific to the drug benefit, including:

- Guaranteed issue – PDPs, and the MA-PD plans, must accept all eligible enrollees who reside in their service area, regardless of age or health status.
- Uniform benefits and premiums – Plans must provide all their enrollees with the same benefits and charge a community-rated premium, which is the same for all enrollees in that region.
- Formulary protections – Plans' formularies must include two drugs from every therapeutic category and class, with only a few exceptions. Plans must also develop the formulary with the help of a pharmacy and therapeutic committee that includes practicing pharmacists, physicians, and an expert in geriatric care. This committee will use the best scientific evidence on drugs' safety, efficacy, and side effects to enhance quality while controlling costs. CMS is working with U.S. Pharmacopeia to develop a model therapeutic categories and classes of drugs, and is also developing guidance on all major aspects of a drug benefit to assure that drug coverage reflects modern medical practice and does not discriminate against any particular type of beneficiary.
- Grievance and appeals requirements – Plans will be required to have a grievance and appeals process that allows beneficiaries to challenge denials based on the formulary. A successful challenge would result in the plan granting what is called an exception, under which, a non-formulary drug could be covered, or a non-preferred drug could be covered

under the terms applicable for a preferred drug under certain conditions. We are proposing that plans have reasonable flexibility to design their exceptions criteria. As part of this process, the prescribing physician would have to determine that the preferred drug (or all the formulary drugs) either would not be as effective for the individual, or would have adverse effects for the individual, or both. Physicians and authorized representatives (such as a family member) can assist beneficiaries in challenging a plan's formulary or its tiered cost-sharing, though, by law, only the enrollee or authorized representative can file an appeal to an outside, independent entity.

- Information – Plans must provide a wide range of information to beneficiaries, including a summary of benefits, how to access the benefits, how the formulary works, and how the plan's medication therapy management program works. They must also provide, upon request, information on the grievance and appeals process and how the plans have performed in this area. As part of our efforts to inform beneficiaries, Medicare also expects to continue many of the features of our current "Price Compare" program for drugs, so that beneficiaries can find the best prices on the medicines they need, as well as learn about other ways to save like substituting less costly generic drugs.
- Customer service – Plans must respond to beneficiary questions in a timely manner, including responses through a toll-free telephone number and by placing information on the Internet. They must also provide beneficiaries with a clear explanation of their benefit use and how much prescription drug spending they have incurred during the year, as well as how close they may be to the catastrophic coverage benefit.
- Pharmacy access – Plans must assemble broad networks of retail pharmacies to provide convenient access for beneficiaries, such that 90 percent of urban enrollees live within 2

miles of a network pharmacy, 90 percent of suburban enrollees live within 5 miles, and 70 percent of rural beneficiaries live with 15 miles.

- Cost management – Plans are required to have cost management programs that save beneficiaries money with tools such as promoting the use of generic drugs and more cost-effective therapeutic substitutions.
- Therapy management – Plans must have medication therapy management programs to help beneficiaries who have multiple chronic conditions, use multiple drugs, and expect to have high drug costs make sure they are taking safe combinations of drugs and using the drugs properly.
- Generic drug information – Plans and pharmacists are required to inform beneficiaries at the point of sale if they could save money by using a generic drug instead of a more expensive brand name drug. Generic drugs are certified by the Food and Drug Administration as just as safe and effective as their brand name counterparts, yet they often cost a fraction of the brand price. As noted above, Medicare has already started providing information on less costly alternative drugs and intends to continue to do so.
- Privacy – Plans must maintain privacy and confidentiality of patient records.
- Collecting satisfaction data – Plans are also required to participate in consumer satisfaction surveys, which allow enrollees to rate their experience with plans. The ratings will be published in Medicare's comparative plan brochures and provide key information for beneficiaries to use when choosing plans.

Low-Income Subsidy

One of the major points I would like to emphasize is the substantial additional assistance available to lower income individuals with Medicare. Under the proposed rule, it is estimated that nearly 11 million beneficiaries with limited incomes and assets will participate in the low-income subsidy, receiving substantial additional help from Medicare. About 6.4 million "dual eligible" low-income beneficiaries will pay no premium, or a limited premium, no deductible and nominal co-pays or as little as $1 or $3 per prescription. For these beneficiaries, ***the Medicare benefit will pay, on average, more than 95 percent of their drug costs.*** Of the "dual eligible" beneficiaries, about 1.5 million who are institutionalized are totally exempt from cost sharing. They pay no premiums, or a limited premium, no deductibles, and no co-payments.

About 3 million Medicare beneficiaries who are not full-benefit dual eligibles, but whose incomes are less than 135 percent of the federal poverty level ($12,568 for an individual and $16,861 for a couple in 2004) and who have limited assets will also pay only a few dollars per prescription, with no premium, or a limited premium, and no deductible. ***Medicare will cover 95 percent of their drug costs on average.***

For about 1.5 million beneficiaries with incomes less than 150 percent of the federal poverty level and assets up to $10,000 (or $20,000 if married) in 2006, the Medicare benefit calls for 15 percent co-pays with a sliding-scale premium, ***covering 85 percent of their drug costs on average.*** Among all enrollees receiving a subsidy, we expect the new comprehensive drug benefit to attract more than 1 million beneficiaries with limited means who, while eligible for Medicaid benefits (including QMB, SLMB and QI benefits), have not previously enrolled.

Altogether, with the straightforward means test proposed in the rule, about a third of all Medicare beneficiaries are eligible for low-income assistance with no gaps in coverage, and limited, or no premiums, deductibles, or co-payments. This coverage is expected to be worth almost $3,500 on average in 2006 and can mean tremendous savings in drug costs. For example, beneficiaries with incomes below 135 percent of the federal poverty level and meeting the asset test can get a lifesaving drug that costs $40,000 or more for at most $60 per year.

We believe that most people eligible will apply for the low-income subsidy and enroll in a plan offering prescription drugs because of the high value of the drug benefit and the unprecedented outreach activities by Medicare and its partners, particularly the Social Security Administration (SSA). This includes about a million beneficiaries who are also eligible for Medicaid, but who previously have not enrolled. To make sure these people can receive drug coverage January 1, 2006, we are working with SSA and the States to have the systems in place so that eligibility determination for the low-income subsidy can be done beginning in mid-2005. In the spring of 2005, SSA, CMS and our partners will begin comprehensive community-based communication efforts to reach the people who are potentially eligible for the low-income subsidy and encourage them to complete a timely application and enroll in a plan offering prescription drug coverage early in the open enrollment period.

Asset Test

The MMA requires CMS to utilize an asset test in determining whether certain low-income beneficiaries are eligible to receive the comprehensive assistance available under the new drug

benefit. The public should know that this asset test specifically does not count items such as the family home, household goods, personal effects, vehicles, burial plots, and a number of other types of resources. CMS has proposed a straightforward asset test that would count only liquid assets such as stocks, bonds, checking and savings accounts, plus real estate holdings other than a primary residence, in determining a beneficiary's qualification for the low-income subsidy. We have also proposed a methodology for verifying income and resources that would eliminate the need for extensive paper documentation.

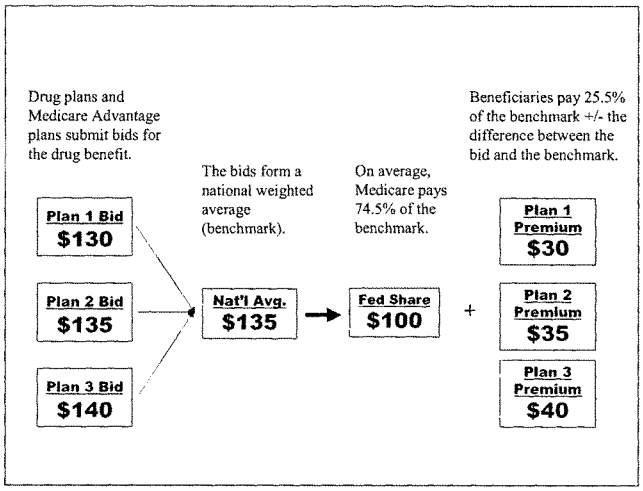
Competition and Lower Drug Prices

The proposed drug benefit rule describes a competitive process for Medicare beneficiaries to pay low premiums, have access to low drug prices, and receive high-quality pharmacy services. The process includes direct Medicare oversight to make sure that the costs and quality of plan bids reflect plans' actual costs.

Beneficiary premiums for the new drug benefit will be determined through a competitive bidding process. The premiums for standard coverage are expected to average in the range of $35 per month in 2006. The specific premium for each plan will be determined by its bid.

By law, and as reflected in the proposed rule, all PDPs and MA plans wishing to provide a drug benefit will submit a bid for the cost of providing the drug benefit to a typical beneficiary in the area they seek to serve. The typical beneficiary will be a statistical average of age and health status for the nation. CMS will review the bids, and the portion of all the approved bids related to basic benefits will be compiled into a national weighted average, which serves as a benchmark

for purposes of setting premiums. The weights will be the plans' enrollment shares in the prior year. For the first year of the program, CMS has proposed a system to estimate weights. The premium for each plan's drug benefit will be 25.5 percent of the benchmark, plus or minus any difference between the benchmark and the plan's bid.



Note: This illustration is slightly simplified and liberally rounded. It assumes equal enrollment weight on each of the five plans and bids for basic benefits only. Technically, an adjustment factor modifies the beneficiary premium percentage to account for reinsurance payments, which are not included in the plan bid amount. However, the purpose of that adjustment factor is to ensure that, on average, the premium represents on average 25.5 percent of the total cost of the benefit, including reinsurance, which is reflected in the graphic.

PDPs seeking to serve the Medicare population will negotiate discounts with manufacturers that they must pass on to beneficiaries in the form of lowered premiums or improved services in order to compete for beneficiaries. Plans that fail to secure highly competitive prices will not be able to offer attractive premiums to beneficiaries, and will lose market share to plans that do a better job of lowering prices.

Competition among private plans to secure favorable drug pricing has been a successful model for other government programs, including the Federal Employees Health Benefits Plan (FEHBP). FEHBP leaves price negotiations up to the private plans that provide coverage for all enrollees, including federal retirees.

As risk-bearing insurers, the new drug plans and MA plans will have every incentive to drive hard bargains with drug manufacturers. Consequently, CMS and the Congressional Budget Office (CBO) expect that the private negotiations between plan sponsors and drug manufacturers will achieve comparable or better savings than direct negotiation between the government and manufacturers, as well as coverage options that better reflect beneficiary preferences. Competition, therefore, will be used to the advantage of beneficiaries and is expected to lower the prices they pay.

Medicare will empower and support beneficiaries in "comparison shopping" by providing specific information on premiums, covered drugs and their prices, and pharmacies and pharmacy services. The competition engendered by making this type of information public has acted to substantially lower prices in the Medicare approved prescription drug discount card program from levels previously borne by our seniors and we expect similar competitive forces to push prices down under the Part D drug benefit.

Using competition to drive price negotiation will maximize savings on drug prices, as well as, or better than when government does direct price negotiation. For example, Medicare approved discount drug card sponsors are realizing higher discounts than the California's Medicaid

program. Until recent reforms made by the MMA, Medicare's prices for drugs currently covered under Part B, and paid for based on rates set by the Federal government, consistently exceeded market averages by significant amounts. We expect that risk-bearing private plans will have strong incentives to negotiate price discounts for such drugs and that the Secretary would not be able to negotiate prices that further reduce Federal spending to a significant degree. And since drug plans are exempted from Medicaid's best price rules, they can negotiate better prices than those paid under Medicaid without having to extend the discounts elsewhere, providing further incentives to do better than government price regulation.

In addition to price negotiation, plans will use a range of formulary design tools and drug utilization management techniques to reduce total spending. Together, we anticipate discounts and cost management savings of 15 percent in 2006, 17 percent in 2007, 19 percent in 2008, 21 percent in 2009, and 23 percent in 2010. The increase over time is due to the market maturing and seniors migrating to more efficient plans, and accounts for the fact that lower drug costs may increase drug utilization for many beneficiaries.

In addition, beneficiaries will also have formulary coverage and pharmacy services that are more responsive to their own preferences than in a government-run plan. In a government run system with a single, set formulary, patients may encounter situations where it is not possible to obtain coverage for the drugs they need. Thus, the approach we are adopting is intended to maximize price discounts while assuring up-to-date coverage of the drugs that beneficiaries prefer, not the drugs that the government chooses in order to limit costs. CMS is seeking comments on steps that will achieve the maximum drug savings possible, without compromising beneficiaries'

access to the medicines they need. For example, the proposed rule seeks comment on how to best design the drug benefit information, including personalized information on drug prices and information about formularies and pharmacies, so beneficiaries will be able to know how much they will have to pay for their drugs, similar to the information currently provided by Medicare for the Medicare approved drug discount card program.

As required by the MMA, CMS has worked with the U.S. Pharmacopeia to establish model guidelines for the categories and classes of drugs to be included in plan formularies. The guidelines are a starting point for structuring formulary categories and classes. However, they allow plans the flexibility to develop their own formularies, which CMS will review to ensure adequacy and nondiscrimination according to publicly reviewed principles that make sure patients have reasonable access to important drugs. CMS has invited public comment on these guidelines and is also conducting an extensive process for public input on the model formulary classification systems and formulary oversight.

Enrolling in a Drug Benefit Plan

The new Medicare drug benefit is designed to be voluntary. In general, Medicare beneficiaries must choose to enroll in a plan offering prescription drug coverage, either a MA plan offering drug coverage or a stand-alone PDP. This approach is different from the "opt-out" rule that exists in Part B, where people are automatically enrolled in the program when they turn 65 unless they notify Medicare otherwise.

Beneficiaries without drug coverage from some other source, comparable to that offered under the Medicare program, who choose to not sign up at the first opportunity, will face a late enrollment penalty if they enter the program at a later date. This late enrollment penalty is similar to a penalty currently in place for late enrollment in Medicare Part B insurance and its purpose is to encourage beneficiaries to enroll when eligible in order to avoid situations where only the sick sign up for insurance, thus skewing the risk pool for those participating in the coverage.

Coverage for the new drug benefit begins January 1, 2006. Initial open enrollment for the new benefit will begin November 15, 2005, and will run for six months, ending May 15, 2006. In subsequent years, open enrollment will run from November 15 to December 31 for the next benefit year. The enrollment periods for all Medicare plans offering drug coverage and Medicare Advantage plans will run at the same time.

Any full dual eligible individual who fails to enroll in a PDP or MA-PD plan would be automatically enrolled, on a random basis, into a PDP that has a monthly beneficiary premium equal to or below the subsidy amount available to low-income beneficiaries.

The MMA also establishes special enrollment periods (SEPs) beyond the initial and annual periods. Special enrollment periods allow an individual to disenroll from one PDP and enroll in another PDP without penalties, outside of the annual period. Special enrollment periods are available for several reasons, including:

- Involuntarily losing creditable drug coverage, or having such coverage reduced below the level that would qualify it as creditable. Creditable coverage is coverage that is at least equivalent to that offered under the standard Medicare drug benefit. Beneficiaries who do not enroll in a PDP or MA-PD plan when first eligible, but maintain creditable coverage through some other source, such as an employer, would be allowed to sign up for Medicare coverage during an SEP and would not be subject to penalties if their coverage was lost or reduced involuntarily.
- Individuals who are subject to enrollment errors, specifically those caused through misrepresentation, inaction, or error by the Federal government will be allowed to enroll under an SEP.
- Individuals who are determined to be full dual eligibles after the initial enrollment period are provided with an SEP. This would also provide these individuals who have been automatically assigned to a plan the opportunity to change PDPs or MA-PD plans at any time.
- An individual who enrolls in an MA-PD plan upon first becoming eligible for benefits under Part A at age 65 and then discontinues that enrollment and elects coverage under original Medicare and a PDP at any time during the 12-month period beginning on the effective date of the MA-PD plan election is eligible for an SEP.
- The PDP terminates its service area or is terminated in the area in which the individual resides.
- The individual moves out of the plan's service area.
- The individual demonstrates to us, in accordance with guidelines that we establish, that the PDP offering the plan substantially violated a material provision of its contract, or the

PDP materially misrepresented the plan's provisions in marketing the plan to the individual.

- In addition, MMA provides for a continuous open enrollment period for institutionalized individuals throughout the year.

Eligibility Determination Process

Eligibility for low-income subsidies may be determined by state Medicaid agencies or by SSA. Individuals will be able to apply for the subsidy at either agency. SSA is implementing a computer scannable application as well as an Internet based application. As a result, we expect that the States and others partners will use the SSA application and eligibility determination process.

If an individual is determined to be eligible for a subsidy, that determination will remain effective for up to one year. The agency that processes the determinations will determine the manner and frequency for re-determinations and the process for appeals. It is important to remember that people who apply for the subsidy must still enroll in an MA-PD plan or PDP of their choice to access the Medicare covered drug benefit.

Keep in mind that beneficiaries who are dually eligible for Medicare and Medicaid, about 6.4 million, as well as those in a Medicare Savings Program (QMB, SLMB, and QI beneficiaries – about one million individuals) will not have to complete an eligibility application. These beneficiaries are deemed eligible and will automatically qualify for the subsidy. Non-full benefit dual eligible individuals will still need to enroll in a plan offering prescription drug benefits.

We are working closely with SSA as they develop the model, simplified application form and process for determination and verification of an eligible beneficiary's income and resources (based on our straightforward asset test). A draft application has been focus group tested with Medicare beneficiaries and is being revised based upon their comments. SSA is working hard to make sure that the application is readily understandable by beneficiaries.

Beneficiaries will be able to complete the application themselves or with the help of State or other community based support organizations. SSA will accept the applications through the mail or it can be dropped off in person, and beneficiaries can also apply over the phone or on the Internet, making it even easier for community organizations to help them sign up. The application form will consist of an attestation regarding a beneficiary's income and resources. The straightforward asset test proposed by CMS, as discussed above, means that beneficiaries will not have to gather together volumes of files, nor do they need apply in person. In fact, the goal of the application process is to facilitate completing the application at home without the need to visit a government office. SSA and the States will be able to verify most information through data matches. States and SSA may need to request some follow up documentation to verify information, if data matches do not provide the needed verification.

We have convened a workgroup with States, SSA, and CMS to work through a variety of issues regarding implementing the low-income subsidies. We intend to work together to develop a system that:

- ensures timely and accurate data sharing on the deemed population;

- facilitates filing applications via the internet, the telephone, or the mail;
- works with community organizations to help people complete applications;
- minimizes the paperwork burden on applicants; and
- exercises appropriate stewardship of federal funds.

Savings to the States

States are projected to see net savings of about $500 million in 2006 and $8 billion in the first five years of the drug benefit. Net savings are projected for states that provide Medicaid-only coverage, states with Medicaid and state pharmaceutical assistance plans, and states with Medicaid and "Pharmacy Plus" (Section 1115 waiver) plans. The sources of savings are as follows:

- *Medicare drug coverage for dual eligibles:* Starting in 2006, full-benefit dual eligible beneficiaries (Medicare beneficiaries eligible for a state's full range of Medicaid benefits, including drug coverage) will receive most of their prescription drug coverage through Medicare rather than through their state Medicaid programs.
- *New subsidies for state retiree health programs:* As employers, states can qualify for the new retiree drug subsidies available to employers and unions that furnish qualified retiree drug coverage to Medicare beneficiaries.
- *Relief for State Pharmaceutical Assistance Programs:* States that operate State Pharmaceutical Assistance Programs (SPAPs) and "Pharmacy Plus" waivers providing subsidized drug coverage to individuals who will be eligible for the Medicare prescription drug plan will gain substantial savings starting in 2006, when Medicare begins providing very generous coverage for beneficiaries with limited means. As a

result of the savings from beneficiaries who qualify for the low-income Medicare coverage, States can "wrap around" the Medicare benefit to maintain or enhance benefits, at a lower cost to the State. SPAP assistance with beneficiary cost sharing would count toward the out-of-pocket catastrophic threshold. As a result, SPAPs will be able to continue to provide as generous or more generous assistance for the beneficiaries who receive coverage through state programs now, at a lower cost per beneficiary for the States because of the availability of the Medicare drug benefit. States will also be able to restructure existing "Pharmacy Plus" programs to wrap around the Medicare prescription drug benefit.

CMS intends to work closely with States, through comments, the new "SPAP Commission" and many other forums, to ensure that the drug benefit delivers better coverage and lower costs for beneficiaries in light of the individual circumstances of each state.

Retiree Coverage

The MMA contains new subsidies designed to encourage employers and unions to continue providing high quality prescription drug coverage for their retirees. This alternative retiree drug subsidy provides special tax-favored payments to sponsors of qualified retiree PDPs. The retiree drug subsidy program has highly flexible rules that permit employers and unions to continue providing drug coverage to their Medicare-eligible retirees while retaining their current plan designs that are at least equivalent to the standard Part D drug benefit, and using the retiree drug subsidy to reduce the cost of providing generous coverage. That is, total support for retiree drug coverage is likely to increase as financial support from the new Medicare retiree drug subsidy

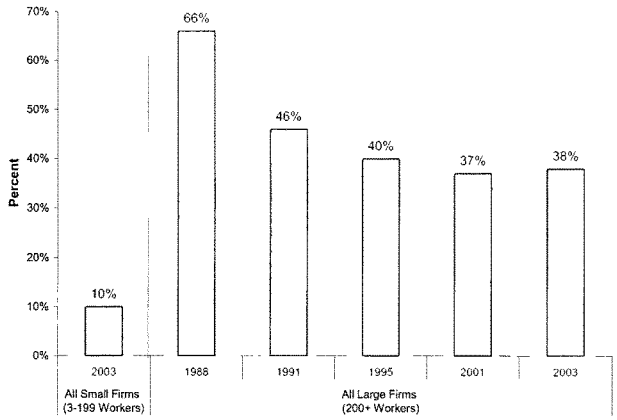
and the Medicare prescription drug benefit augment employer and union contributions. This may result in retirees spending less on average – possibly significantly less - for prescription drug cost sharing and premiums combined, than they would without the new law.

Sponsors of employer and union plans who offer a drug benefit as good as, or better than, Medicare's standard drug benefit will be able to apply for the subsidy, which is estimated to roughly average $611 per beneficiary in 2006. The after tax nature of the retiree drug subsidy payments effectively increases the value of these payments for employers that are subject to the corporate income tax. For firms with a marginal tax rate of 25 percent that translates into a subsidy of $815, and for firms with a marginal tax rate of 35 percent, the value of the subsidy rises to $940. Our proposed rule presents several options on how to define the qualifying criteria for employers and unions who would like to receive the subsidy. We are currently accepting comments on these options and are committed to maximizing participation, preventing windfalls and limiting costs to the treasury.

Retiree coverage has been in decline for many years

Employer-sponsored retiree health insurance has been an important source of drug coverage for many Medicare beneficiaries. However, for well over a decade, the availability and generosity of employer-sponsored retiree health coverage has been eroding, particularly for future retirees. As prescription drug costs have risen, employers have shifted more of those costs to their retirees, and many employers have ceased offering retiree health coverage altogether.

Percentage of Firms Offering Retiree Health Benefits, 1988-2003



Source: Kaiser/HRET Survey of Employer Sponsored Health Benefits: 2001, 2003; KPMG Survey of Employer-Sponsored Health Benefits: 1988, 1991, 1995. The denominator is all firms that offer health benefits to active workers.

In 1988, 66 percent of large employers that offered health benefits to active workers also offered retiree health benefits. In 2003, only 38 percent of large employers offered them. During the same year, only about 10 percent of small firms that offered health benefits to active workers also offered retiree health benefits. The picture is even starker for future retirees, who have been disproportionately affected by most of these changes.

The Retiree Drug Subsidy

Medicare is helping employers continue to provide retiree health care coverage. The new retiree drug subsidy will support employers and unions who continue offering high-quality prescription drug coverage as Medicare's own benefit comes online, or who enhance their coverage by using the new support to offer better coverage at a lower cost. The proposed regulation reflects our

four objectives of: maximizing the number of retirees benefiting from the retiree drug subsidy, avoiding windfalls to employers, minimizing administrative burden, and not exceeding budget estimates. In doing so, our objective is to get the maximum possible increase in support for drug coverage for all retirees, and so we are considering a range of potential options discussed in the preamble of our Title I proposed regulation, each of which may help us achieve our key objectives. We seek comments and are conducting extensive public outreach on how best to accomplish our objectives.

To maximize the continuation and enhancement of retiree coverage, CMS is proposing that the Medicare retiree drug subsidy be designed to be flexible enough to enable employers and unions to obtain the subsidy without disrupting their current coverage. Many employers will be able to continue the same drug plans they offer today, uninterrupted, while receiving a substantial Federal subsidy to reduce their costs. Retirees can choose to enroll or not enroll in the new standard Medicare drug benefit while remaining in their employer or union plan, which may also offer better coverage.

Employers also have the option of declining the retiree drug subsidy and encouraging their retirees to enroll in Medicare's new PDPs, or in an MA-PD plan, while providing them with extra help. These approaches as well can lead to drug savings for both retirees and employers. There are several ways that employers could supplement the standard Medicare drug benefit:

- They may pay for supplemental coverage through an enhanced Medicare plan that fills in more of the cost-sharing, just as employers "wrap around" Part A and Part B Medicare benefits today;

- They may set up their own external supplemental plans and coordinate benefits with the Medicare drug plans, providing extra help with cost sharing;
- They may also choose to provide assistance with the basic drug premium for Medicare; and,
- They may choose to set up special prescription drug plans, or Medicare Advantage plans, for their retirees. CMS plans to use its waiver authority to allow employers to make special arrangements with PDP and MA-PD plans for their retirees. These waivers would allow employers and plans to provide more flexible benefits and to limit enrollment to the retiree population.

Many factors may influence the responses of employers and unions to the new subsidy for retiree drug coverage. As noted above, one critical decision is whether employers will want to remain the primary insurer of retiree prescription drug costs and receive the retiree drug subsidy, or shift to becoming a secondary payer by wrapping around Medicare coverage, with Medicare subsidizing retiree drug costs by becoming the primary insurer. Either way, the actual benefits received by retirees could remain unchanged or increase, but at a lower cost to the employer, making both approaches to comprehensive drug coverage indistinguishable to beneficiaries.

It is important to remember that retirees who choose to continue with their employer-sponsored drug coverage will always be able to enroll in the Medicare prescription drug program at a later date, free from any late enrollment penalties, as long as their employer's drug coverage is at least as generous as the standard Medicare drug benefit.

We are seeking comments from retirees, employers, unions, and others on the best way to implement all of those options in order to reduce retiree drug costs. On June 9 and August 19, CMS held two open door forums, allowing the public to comment on this important aspect of the drug benefit. After an overview of the issues by several panel members, the bulk of the time in these meetings was devoted to public input. CMS also issued a white paper that includes an extensive discussion of these important issues for the August forum and solicited input thereon.

Providing More Comprehensive, Lower-Cost Health Plan Choices through an Enhanced Medicare Advantage Program

The MMA expands the existing options available to Medicare beneficiaries to voluntarily enroll in private health plans. Currently, about 4.7 million beneficiaries are enrolled in these plans, known as MA local plans. The key new benefit is the MMA's new regional contracting option for new MA regional plans. The proposed regulation issued by CMS would propose to implement these and other changes to the MA program. The new regional plans, which will be available in 2006, are structured as preferred provider organizations (PPOs), which have a network of doctors and hospitals that contractually agree to provide health care services at a specified rate but also allow enrollees to go outside the network for care, usually for an additional charge. PPOs are now the most popular type of coverage in the private market in the U.S. In 2002, 52 percent of Americans covered under group health insurance programs were enrolled in PPOs. This is because they provide both coordinated care that reduces beneficiary costs, and broad flexibility in choice of providers if and when beneficiaries need them. Also addressed in the proposed regulation is a new option created by the MMA that allows specialized

plans for Medicare beneficiaries who have special needs, such as the institutionalized, those with Medicaid, and individuals with severe or disabling chronic conditions.

We are working right now to make these new MA options available to all Medicare beneficiaries in 2006. Beneficiaries will receive materials each fall that outline the options available to them and their quality and cost features, and also can get sources for additional information, enabling them to make the choice best suited to their needs.

Beneficiaries Will Get More Savings

Studies show that enrollees in current Medicare+Choice/MA plans not only receive more benefits than beneficiaries who have coverage only in the traditional Medicare fee-for-service (FFS) program only, they also pay less out of their own pockets to receive these benefits. A recent published report found that out-of-pocket payments for beneficiaries in MA plans are 34 percent less than out-of-pocket payments for beneficiaries with FFS Medicare. While out-of-pocket costs (including the Medicare Part B premium) for beneficiaries with FFS with no supplemental coverage average about $2,631 per year, the average for MA enrollees in 2003 was $1,964. Thus, on average, a beneficiary could expect to save about $56 a month as an MA enrollee.[1]

The differences in spending between MA and FFS Medicare are particularly large for beneficiaries with costly chronic illnesses and predictably high medical costs. A CMS analysis of out-of-pocket costs showed that in 2004, enrollees in poor health could expect to save, on

[1] (Marsha Gold and Lori Achman, "Average Out-of-Pocket Health Care Costs for Medicare+Choice Enrollees Increase 10 Percent in 2003," Commonwealth Fund Issue Brief #667, August 2003.)

average, about $1,900 per year by enrolling in an MA plan, as compared to FFS without supplemental coverage. (Unpublished CMS data.)

Reduced out-of-pocket payments make MA plans particularly important for lower income beneficiaries who are struggling to afford up-to-date medical care. For example, beneficiaries with incomes between $10,000 and $25,000 – beneficiaries who usually do not qualify for Medicaid, and who are unlikely to have access to inexpensive retiree coverage to supplement their Medicare coverage – are relatively much more likely to enroll in MA plans. These beneficiaries comprise about one-third of all Medicare beneficiaries, but make up half of Medicare Advantage enrollees. (Based on year 2002 Medicare Current Beneficiary Survey data.) As seniors and people with disabilities struggle with rising out-of-pocket costs for their health care, it is more important than ever to make options available that enable them to lower their medical costs substantially.

Extra Benefits and Other Savings

MA plans typically cover benefits beyond the Medicare range of covered services, and do not limit services to the same extent as Medicare (for example, the majority of MA plans offer unlimited inpatient hospital days). Such extra benefits include additional preventive benefits and wellness services; disease management and care management services for beneficiaries with chronic illnesses or high medical expenses; and dental, vision, and hearing services.

In addition to expanded benefits and lower beneficiary payments for services, MA enrollees may benefit from lower Medicare premiums as well. Eleven percent of Medicare beneficiaries currently live in a county in which there is a MA plan offering rebates on the premiums

beneficiaries pay for Medicare Part B. In three counties in Florida, beneficiaries can choose a plan that has no plan premium and that offers a full reduction of the 2004 monthly Medicare Part B premium of $66.60.

MA plans begin to offer drug coverage in 2006 under Part D. With their ability to secure discounts and coordinate the drug benefit with medical services, MA plans may be able to offer more generous drug coverage and lower premiums compared to stand-alone drug plans.

The MMA has already improved the situation of the average MA beneficiary. Under the revised MA program that will begin in 2006, *all* Medicare beneficiaries will have access to these same types of savings.

Immediate MA Improvements

While many changes in the Medicare Advantage program do not take effect until January 1, 2006, some immediate increases to payments for Medicare Advantage organizations are already improving access to health plan options and reducing costs and improving benefits for Medicare beneficiaries. This increased funding will make up for years of payment updates that were behind the cost increases M+C organizations were facing, which in turn prompted many plans to drop out of the program. In addition, the new law requires these additional payments to be used to lower premiums or improve the benefit package offered by the MA plans.

As a result of these immediate changes, about 3.7 million enrollees in Medicare Advantage plans are seeing improved benefits and lower costs. Premiums dropped for 1.9 million enrollees, and 2

million enrollees had a decline in cost sharing. Many enrollees are benefiting from more than one of these changes in their health plan. In addition, the enrollment-weighted average premium for Medicare Advantage plans dropped from $42 to $31. Further, the percentage of enrollees that will receive some type of drug coverage increased from 78 percent to 80 percent. On average, improvements in the MA benefit package made possible by the MMA outweigh recent increases in the Part B premium.

Overall, 95 percent of the increased funding is being used to help beneficiaries, with:

- 31 percent being used to reduce enrollee premiums;
- 5 percent being used to reduce the amount enrollees pay for cost sharing and co-payments;
- 17 percent being used to enhance existing benefits; and,
- 42 percent of the additional funds being used to strengthen provider networks and ensuring that beneficiaries continue to have more choices of physicians, specialists, and other health care providers.

Benefits and Beneficiary Protections

MA plans must provide all Medicare-covered benefits, and as noted above, they generally provide substantial additional benefits that allow beneficiaries who enroll to lower their costs significantly. Most MA local plans currently provide limited, if any, coverage if their enrollees choose to go outside the network for non-emergency care. And they are not required to have a single deductible or catastrophic limit on enrollee out-of-pocket costs. Beneficiaries in MA regional plans will typically have lower cost-sharing when they remain in network, but they will have more coverage of care provided outside the network that is significantly more generous

than that available in most local plans today. In addition, unlike traditional FFS Medicare with its separate deductibles for Parts A and B, regional MA plans are required to have a single, unified deductible (if they feature a deductible at all), though they may waive the deductible for preventive services and other services. Regional MA plans must also feature a catastrophic limit on out-of-pocket expenditures for in-network services, and a limit for all covered services. MA plans may also offer a prescription drug plan in conjunction with the traditional benefit package.

Regions

Unlike local plans that serve individual counties and groups of counties chosen by the plan sponsor, the new regional PPOs will bid to serve an entire region, which may be a state or multi-state area. The goal of these larger regional markets is to bring more plan options to rural areas by grouping them with the urban areas that have traditionally attracted managed care plans under the Medicare+Choice program. The MA regional plans may operate in more than one region, or even nationally. Following a market survey that will be completed later this year, as well as public comment, the Secretary will establish 10 to 50 MA regions, designed to maximize plan participation and quality and cost savings for beneficiaries. All beneficiaries will have access to a choice of such plans, regardless of the region in which they live. On July 21, 2004, CMS held a public meeting in which interested parties were allowed to offer their perspectives on establishing the MA regions. The Agency is cognizant of the importance of establishing these regions in a timely manner and is working to meet the statutory deadline of January 1, 2005. We will continue our public outreach efforts as we consider how to finalize this important aspect of the rule.

Financial Incentives for Regional PPOs

Risk Corridors

To encourage the offering of regional MA plans, MMA provided for risk sharing for Part A and B health benefits to be in effect for 2006 and 2007. Risk corridors will allow the government to share in any unexpected gains or losses that the plans incur and help plans in the early years of the regional plan program while they gain experience covering the Medicare population on a regional basis. With the risk corridors, a target amount of plan spending is set to equal the total payments to plans from the government and enrollee premiums, minus the plan's administrative costs assumed in its bid. Actual costs at the end of the year are then compared to this target amount. The risk corridors are symmetrical in that the government pays plans if costs are above the target and recoups its share of the savings when costs are below the target.

The plan is fully at risk for the first 3 percent of costs above or below a target amount.
The plan and the government share 50 percent of costs/savings that are 3 to 8 percent off the target. The government pays/keeps 80 percent of the costs/savings that are more than 8 percent off the target.

Plan Entry and Retention Fund

Starting in 2007, a plan entry and retention fund will be created consisting of $10 billion in appropriated funds plus additional monies from the bidding process (half of the government's portion of the savings based on the difference between the regional plans' bids and the regional bidding benchmarks). The fund is available through 2013 and can be used several ways:

National Bonus. If a health plan enters the program nationally (by bidding to provide a MA plan in all regions), then its benchmark payment in each region is increased by 3 percent. This bonus is available for one year only, and it is not available if a national plan was available the prior year.

Regional Plan Entry Bonus. If no regional MA plans serve a given region in one year, then the Secretary may increase payments for plans in that region for the following year. The Secretary has wide discretion to set the parameters of the regional plan entry bonus.

Regional Plan Retention Bonus. If plans signal that they are going to leave a region, the Secretary may increase the benchmark in that region in an effort to keep the remaining plans and attract new bidders. Two additional conditions must be met: the exits must result in fewer than two regional organizations being available, and the MA enrollment share in the region must be less than the national MA enrollment share. The Secretary has discretion to increase the benchmark (within certain limits), and the increase can last for up to two years.

All of the above payments are subject to the overall budget constraints for the plan entry and retention fund. The Secretary and CMS actuaries must certify that there is enough money in the fund to cover the payments, and they may limit enrollment in regional plans receiving the payments to make sure enough money is available. The Secretary must also periodically report to Congress about how the plan entry and retention fund has been used and the market conditions in regions that make its use necessary.

Essential Hospitals

One of the challenges that MA plans have faced in operating in rural environments is establishing an adequate network. Beginning in 2006, regional MA plans that are unable to successfully contract with certain essential hospitals are eligible to receive limited assistance to establish an adequate network. If specific criteria are met, CMS is authorized to pay additional amounts to that hospital from the Federal Hospital Insurance Trust Fund. These funds are limited to $25 million in 2006, with inflationary updates in succeeding years.

An essential hospital means a general acute care hospital that CMS determines the MA regional plan must have under contract in order to meet access requirements. The determination of essential hospital status is only conferred after appropriate application to us by an MA organization offering an MA regional plan. Finally, in order to qualify for the additional payment, the essential hospital must demonstrate to our satisfaction that the amounts normally payable are less than the hospital's costs for providing services to MA regional plan enrollees. In addition, there is a minimum amount to be paid by the MA plan and a maximum total payment, including the Medicare payment to the essential hospital.

The intent of the additional payment to essential hospitals is to facilitate an MA regional plan's ability to meet network adequacy requirements across large geographic areas—an MA region. Such an essential hospital would become part of the contracted network of providers of the MA regional plan and in-network enrollee cost-sharing rules would apply. CMS anticipates this provision to be particularly helpful to rural beneficiaries. The proposed regulation seeks

comments on other approaches within our statutory authority to support effective access for rural beneficiaries in all parts of a PPO region.

Improved Quality and Patient Safety

Under the MMA, CMS is moving to increase patient safety and quality of care through a number of initiatives. The focus is on obtaining better results for the dollars we spend. To accomplish this, among other things, the statute requires the National Committee on Vital and Health Statistics (NCVHS) to develop recommendations for electronic prescribing standards. E-prescribing is a proven method of reducing medication errors and CMS looks forward to working on this important effort. NCVHS has consulted with physicians, hospitals, pharmacists and pharmacies, pharmacy benefits managers (PBMs), State boards of pharmacy and medicine, Federal agencies and other electronic prescribing experts in its work to develop uniform standards. The law also requires a pilot project once the Secretary has adopted or announced the initial standards. The pilot will run from January 2006 through December of that year, and it will be completed prior to the promulgation of the final standards. We expect that NCVHS will shortly be communicating its recommendations to the Secretary.

Medication therapy management services are also called for under MMA. The statute allows a broad range of services under this provision. The purpose of medication therapy management is to provide services, distinct from dispensing drugs, that optimize therapeutic outcomes for targeted beneficiaries.

Medication therapy management may include elements designed to promote (for targeted beneficiaries):

- Enhanced enrollee understanding--through beneficiary education counseling, and other means--that promotes the appropriate use of medications and reduces the risk of potentially adverse events associated with the use of medications.
- Increased enrollee adherence to prescription medication regimens (for example, through medication refill reminders, special packaging, other compliance programs, and other appropriate means).
- Detection of adverse drug events and patterns of overuse and underuse of prescription drugs.

In order to promote these elements and optimize therapeutic outcomes for targeted beneficiaries, we envision a broad range of simple to complex services falling under the heading of medication therapy management services. In addition to those mentioned in the statute, services could include, but not be limited to, performing patient health status assessments, formulating prescription drug treatment plans, managing high cost "specialty" medications, evaluating and monitoring patient response to drug therapy, providing education and training, coordinating medication therapy with other care management services, and participating in State-approved collaborative drug therapy management. We expect that these services will help increase the effectiveness of medications used by beneficiaries and reduce the number of adverse events associated with drug interactions or reactions.

CMS has also begun an exciting program designed to improve care for beneficiaries with chronic conditions. Under Section 721 of the MMA, CMS will contract with a number of disease

management programs to provide services to beneficiaries with a select range of chronic conditions. These disease management programs will use a broad range of proven and promising techniques to help beneficiaries comply with physician treatment plans, drug regimens and lifestyle changes in order to reduce the number of hospitalizations and acute incidents that they experience. The disease management organizations' payments will depend entirely on their ability to prove reduced costs to the program. The statute provides for a broader application of the Chronic Care Improvement Program. In addition, all MA plans will be required to use disease management techniques to help beneficiaries with chronic conditions and their physicians better manage their health. The increased quality of information that these disease management programs will provide to patients and their physicians, along with their reliance on proven standards of care could result in Medicare beneficiaries receiving higher quality, more effective care at lower costs overall.

Through clear, consistent and integrated communications and effective partnerships, the Quality Improvement Organizations (QIOs) are continuing to work with providers, stakeholders, purchasers/payers, and the media to help stimulate widespread change in attitudes and behavior with regards to the importance of ongoing quality and safety improvement in health care. There is tremendous opportunity for improving quality and safety in health care for seniors, particularly involving prescription drugs. For example, a recent study of nearly 400 hospitalized elderly patients reported in the Annals of Pharmacotherapy found that nearly 92 percent of patients had received a medically inappropriate prescription.[2]

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[2] Hanlon, Joseph T., et. al., "Inappropriate Medication Use Among Frail Elderly Patients," in *The Annals of Pharmacotherapy*, vol. 38, no. 1, pp. 9-14.

Specifically for the Part D drug plan, the QIO's, working with the Agency, will begin work with PDP, MA-PD plans, and fallback plans, (referred to as drug plans), and providers to help promote higher quality care for beneficiaries enrolled in these plans. QIOs will develop quality improvement projects that measure performance of the drug plans and providers with whom they work. Performance measures will be organized according to the Institute of Medicine's (IOM) six identified criteria for quality: *Safe, Effective, Patient centered, Timely, Efficient, and Equitable.*

CMS will monitor the QIOs' work with these plans and their ability to disseminate important quality improvement information learned in their efforts. The QIOs will also identify and offer technical assistance to all drug plans that serve beneficiaries within their state to implement quality improvement programs.

Timely Implementation

Implementing all of these new benefits and programs involves a tremendous amount of work. Because Medicare has never before offered outpatient prescription drug coverage, CMS must engage in a new line of business to establish these benefits. To implement regulations for these programs CMS must propose regulations to the public, accept and respond to comments, and issue the final version. CMS is hiring a large number of new people with specific knowledge and skills (e.g., administration of pharmacy benefit programs and employer benefits), preparing to build computer systems, negotiate and execute complex contracts, institute monitoring mechanisms, and expand our current beneficiary education and support program. To help us in hiring the right people, CMS is participating in an innovative public-private effort with several

leading human resources firms, including Monster Government Solutions, ePredix, CPS Human Resource Services, AIRS, Brainbench, and Korn/Ferry International. These entities will be donating their services to analyze CMS' hiring process and make suggestions for improving things so that the Agency can employ the most qualified persons in a timely fashion. The 2006 deadline for all of this to happen is very ambitious and CMS has been diligently laying the groundwork for that opening day since the moment the legislation was signed.

The Medicare Approved Prescription Drug Discount Card – A Bridge to the New Benefit

While working on the myriad of tasks required to implement the new drug benefit and improve the MA program, CMS has already implemented an important program to offer some immediate relief to seniors with high drug costs. The Medicare Approved Prescription Drug Discount Card program, announced only a few days after President Bush signed the MMA, is now offering concrete assistance to Medicare beneficiaries with little or no drug coverage.

To date, well over 4 million beneficiaries have enrolled in the drug card program. The beneficiaries who are receiving real savings now represent well over 50 percent of the 7.4 million seniors who CMS estimated would sign up for the card by December of 2005.

Medicare beneficiaries began signing up for drug cards on May 3, with discounts beginning June 1, 2004. Since that time there has been steady growth in beneficiaries signing up for the card with drug card sponsors now receiving an average of well over ten thousand enrollees every day. As of September 2, more than 4.3 million beneficiaries have enrolled in a card program. Well over 1 million of those beneficiaries are receiving the $600 low-income credit. Approximately

2.4 million beneficiaries were automatically enrolled in a card by their health plans and nearly 350,000 were auto-enrolled through their state pharmacy assistance program (SPAP), with an additional 13,000 being sent pre-filled applications by their SPAP.

A recent Kaiser Family Foundation study reported that top Medicare drug cards provide savings as compared to retail of between 19 and 24 percent for urban retail prices, 17 to 22 percent for rural retail, and 27-32 percent urban mail order.[3] A study released in July by The Lewin Group analyzing 150 drugs most frequently used by seniors found that individuals participating in the Medicare drug discount card program beginning in the summer of 2004 will save an average of $1,247 on their prescription drug purchases before the program concludes at the end of next year.[4] A June study by the American Enterprise Institute found that the Medicare approved drug discount cards offered discounts of 8–13 percent off of brand name retail prices and 15-23 percent on mail order brand name drugs.[5] A study by the Consumers Union found that Medicare approved drug discount cards available in California consistently provided drug prices *lower* than those available under the Medi-Cal program. Medi-Cal prices are already 20 percent lower than those typically available in a retail setting and the study concluded that prices under the card

[3] *Medicare Drug Discount Cards: A Work in Progress*, Prepared for the Henry J. Kaiser Family Foundation by Health Policy Alternatives, Inc. Available at: http://www.kff.org/medicare/loader.cfm?url=/commonspot/security/getfile.cfm&PageID=44587

[4] *Assessment of Beneficiary Savings in the Medicare Drug Discount Card Program*, Prepared for the Healthcare Leadership Council by Jennifer Bryant, John Corea, and Allison Sydlaske of The Lewin Group Available at http://www.lewin.com/NR/rdonlyres/e3ojwukgg5tthdntqdykfairad7nn676zrmeafuqoxjpwaongc6fgl3dn3p7mygqytd cndur2nfm5m/LewinHLCStudy.pdf

[5] *Private Discounts, Public Subsidies: How the Medicare Prescription Drug Discount Card Really Works*, Prepared by the American Enterprise Institute, Joseph Antos and Ximena Pinell. Available at: http://www.aei.org/docLib/20040616_book779text.pdf

program could be reduced by as much as 10 percent beyond Medi-Cal's rates.[6] The results of these private studies all compare well with CMS studies, which have shown similar savings.

Beneficiaries should know, that signing up is as simple as calling 1-800-MEDICARE with the information on their prescriptions, their preferred pharmacy, and their annual income. The customer service representatives at our call centers can walk them through their drug card options and the process of enrolling in an appropriate drug card in just a few minutes. The person can quickly enroll in a card and begin realizing savings on the medications they need.

Education and Outreach

CMS is aware that one of the greatest challenges will be to accurately inform beneficiaries about these new options and assist them in taking advantage of these services. CMS has taken many steps to increase beneficiary assistance and seeks comments on how to further improve our ability to help beneficiaries get the personalized, one-on-one assistance they need to get the most out of Medicare's expanded benefits and out of our increasingly modern, but increasingly complex, health care system. These activities will build on our broad experience and success using the National Medicare & You Education Program begun in response to the Balance Budget Act of 1997. We will employ the comprehensive elements of this Program to ensure that people with Medicare know about these new benefits and choices, and understand how to make informed decisions to enroll in the health plans and the prescription drug plans that offer these benefits. Elements of this Education Program and examples of consumer products and assistance include:

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[6] *Medicare Discount Drug Card Savings in California: Technical Summary*, Prepared by Consumers Union for California Healthcare Foundation. Available at: http://www.chcf.org/documents/insurance/MedicareDiscountDrugCardSavings.pdf

- Publications for People with Medicare

  CMS intends to continue and enhance the use of targeted publications and informational mailings to help people with Medicare understand the new benefits and how to get the most out of these benefits. These mailings and related publications will also be available online at www.medicare.gov. Numerous mailings have already been sent to people with Medicare to help them learn about, and enroll in, the Medicare-approved drug discount cards and the formal drug benefit coming in 2006.

- Medicare & You Handbook

  Additionally, each fall CMS mails *Medicare & You* handbooks for the next plan year to beneficiaries and stakeholders. Handbooks are offered in English and Spanish, and are also available in Braille and large print. CMS also mails *Medicare & You* to new enrollees throughout the year on a monthly basis.

- 1-800-MEDICARE Toll-Free Telephone Services

  CMS undertook recent enhancements at 1-800-MEDICARE so that people with Medicare can get additional support in identifying the best drug plans and health plan options for their needs. CMS has increased the number of customer service representatives (CSRs) from several hundred to 3,000 and expects to maintain this number of trained CSRs to handle the unprecedented number of callers in a timely and effective manner. CMS has added voice messages to help callers be better prepared when they reach a customer service representative, further reducing call waiting and call handling time.

- www.medicare.gov

  The most significant recent enhancement to the Medicare web site is the release of information on the new Medicare-approved drug discount cards. The Prescription Drug

and Other Assistance Programs (PDAP) section of www.medicare.gov provides information on public and private programs that offer discounted or free medication, programs that provide help with other health care costs, and Medicare health plans that include prescription coverage. Enhancements and updates to the site will continue frequently to ensure users get the accurate information they need, easily and in a timely fashion.

- National Publicity Campaign

  The CMS national multi-media campaign utilizes television, radio, print, and Internet advertising, to inform and motivate people with Medicare and their caregivers to call 1-800-MEDICARE, visit www.medicare.gov, and refer to the *Medicare & You* Handbook for answers to their Medicare questions. For example, the last week of April 2004, CMS initiated a new TV and print ad campaign to introduce the Medicare-approved drug discount cards, and launched new advertising in late August to further encourage enrollment in the cards.

- Public Private Partnership

  CMS currently partners with more than 140 organizations and groups on education and outreach efforts. We have taken steps to expand the partnership base to provide stronger entrée into community and faith-based service organizations, health information providers, and aging outreach centers – groups that work with Medicare beneficiaries who are most in need.

- Community-Based Outreach

  CMS also supports non-profit organizations to help educate and assist low-income beneficiaries who may otherwise be hard to reach. We recently announced the

availability of $4.6 million in grants and contracts to community-based organizations, local coalitions, and national organizations to help people with Medicare learn about the $600 in transitional assistance money available through the Medicare-approved drug discount cards. CMS continuously looks for the most effective ways to work with State Health Insurance and Assistance Programs (SHIPs), as well as private organizations, to help further improve our personalized outreach and support.

- Regional Education about Choices in Health (REACH)

  CMS' ten Regional Offices (ROs) manage the Regional Education about Choices in Health (REACH) program to cultivate community-based partnerships with organizations that use existing outlets to conduct education activities for populations with barriers caused by differences in language, literacy, location, low income and/or culture. Many REACH partners serve beneficiaries who prefer and need in-person information and assistance in familiar, community settings.

- State Health Insurance Assistance Programs – SHIPs

  For beneficiaries with unique and complex issues and who require face-to-face personalized assistance, CMS has also enhanced its partnership with the State Health Insurance Assistance Programs (SHIPs). CMS recently announced that HHS will award $21.1 million this year, and another $31.7 million next year, to the SHIPs, reflecting the increased emphasis on one-on-one advice and counseling for people with Medicare. The SHIPs are an essential resource in helping beneficiaries learn about the changes to Medicare and will be able to use the additional funds to equip local organizations with the tools needed to answer beneficiaries' questions.

- Training for Information Intermediaries

CMS has developed a national training program to educate and train CMS staff, partners, and information intermediaries who are responsible for educating people with Medicare about their health care choices, benefits, rights and protections. Training is made available in a variety of different ways including web-based, face-to-face and on CD-ROM.

- Consumer Research and Performance Measurement

  To help ensure that all of these education and outreach efforts effectively reach people with Medicare with relevant and understandable information, CMS conducts consumer research. This research includes both formative research to determine what information different segments of our population want and how to convey it, and testing of publications, material for the website and media messages and strategies.

Program Assessment

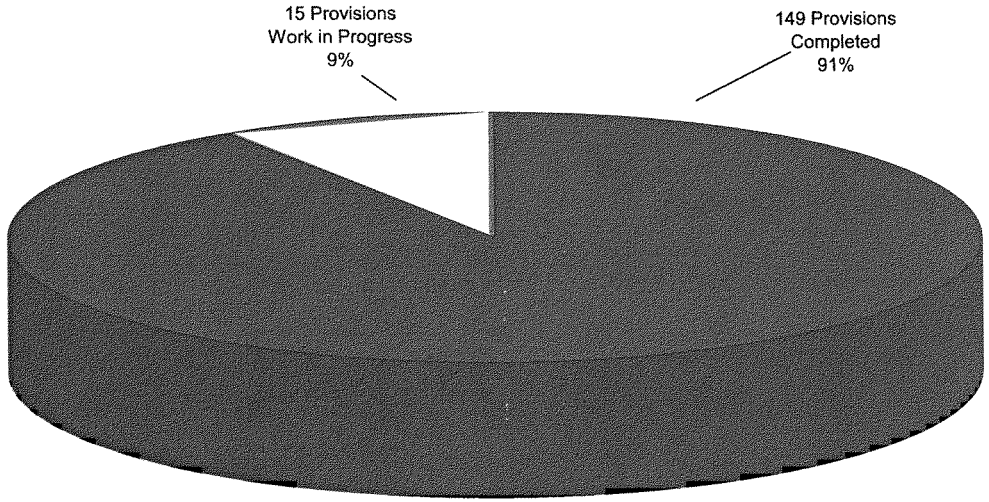
A fundamental building block of the National Medicare & You Education Program is a multifaceted approach to assess the overall strategy of educating beneficiaries about Medicare. These performance measurement activities identify what is working well and what needs to be improved in each of the activities used to communicate information about Medicare. The performance measurement system addresses all elements of NMEP. The assessment information is used for continuous quality improvement of each element as well as to improve how well the different elements work together. The channel-specific measurements cover: print materials; toll-free telephone services (1-800-MEDICARE); the internet (www.medicare.gov); Regional Education about Choices in Health (REACH); National Alliance Network; national training and support for information givers; and enhanced beneficiary counseling from the State Health

Insurance Assistance Programs (SHIP). We have also conducted case studies in six communities to study the evolution of the National Medicare & You Education Program in these communities. The case studies add to our other performance measurement activities by providing information about how all of the elements of the education program work together at the local level.

Summary

Beginning in 2006, Medicare beneficiaries will have access to higher quality, more affordable, more comprehensive and integrated modern health care. They will have choices about how they obtain those benefits, and their market power will be used on their behalf to lower the prices they pay. CMS looks forward to working with the Congress in implementing these important new programs and we emphasize, again, our strong desire for public participation and comment in this process. I thank the Committee for its invitation to come here today to discuss these, the most important changes in Medicare's history, and look forward to any questions you may have.

CMS Progress in Completing Medicare Modernization Act Provisions with Effective Dates From Enactment, December 8, 2003, through August 31, 2004



Senate Finance Committee
Hearing on "Titles I and II: Features of the Proposed Regulations"
September 14, 2004

These are the answers for the record to be inserted into the transcript for the hearing.

SEN. GRAHAM: Could you submit for the record your estimate of how components of the Medicare reform bill, by classes of beneficiaries, will affect their costs of uncovered services?

INSERT: Page 69, line 20

DR. McCLELLAN: See the table below:

Estimated Average Enrollee Total Drug Spending, Drug Spending Paid for by Medicare Drug Benefit, and Drug Benefit Premium, CY 2006 and CY 2010

	Estimated average annual drug spending	Estimated average annual drug spending paid for by the Medicare drug benefit*	Estimated average annual premium
2006			
Enrollees Not Receiving Low-Income Subsidy	$2,936	$1,437	$428.
Enrollees Receiving Low-Income Subsidy	3,649	3,476	0 or $214**.
2010			
Enrollees Not Receiving Low-Income Subsidy	3,852	1,890	$564.
Enrollees Receiving Low-Income Subsidy	4,794	4,518	0 or $282**.

* Average annual drug spending paid for by the Medicare drug benefit reflects on average how much the Medicare drug benefit will payout per beneficiary. This is different from the amount of drug costs the Medicare drug benefit would payout for a beneficiary with average total drug spending, due to the interaction between the distribution of drug spending and the deductible and cost-sharing structure of the Medicare drug benefit. We also note that the average drug spending paid for by the Medicare Part D plan reflects drug costs reimbursed by the plan and does not include PDP or MA-PD administrative costs.
** Low-income subsidy enrollees with income between 135 percent and 150 percent of FPL face a sliding scale premium based on income, which is estimated to average $214 per year in 2006 ($282 in 2010). Other enrollees in the low-income subsidy pay no beneficiary premium at all, as long as they select a PDP or MA-PD with a premium that does not exceed the greater of the low-income benchmark premium or the lowest PDP premium for basic coverage for the region and as long as they enroll within the initial enrollment period or have met creditable coverage requirements.

SEN. BINGAMAN: Could you get back to me, maybe, with a little better sort of analysis as to, if in fact we are investing $23.4 billion, or transferring that much to health plans in this period, could you detail, what are the benefits that beneficiaries receive as a result of that?

INSERT: Page 102, line 24.

DR. McCLELLAN: Some have erroneously claimed that managed care companies will be receiving an extra $25 billion in Medicare payments between 2004 and 2009, with only $1.4 billion of this amount going towards benefits. This statement is incorrect.

We project that the MMA will result in additional program expenditures of $24.8 billion over the six-year period 2004-2009, or about $37 per Medicare Advantage enrollee per month. This will be used to finance Part A and B benefits, reduce cost sharing for Medicare enrollees, and/or pay for extra benefits for plan enrollees (benefits not covered by Medicare but available through MA plans). This reflects the costs associated with increased enrollment in the Medicare Advantage program. Under the new law, Medicare Advantage enrollment is expected to increase two-fold, from 11% to 33% of beneficiaries through 2010.

The $1.4 billion quoted in the Federal Register for the provision of benefits **beyond** basic Part A and B benefits is actually incorrect and we are working to correct this. According to the additional analysis we have completed to date, we expect the amount of extra benefits provided to be much higher. Examples of these extra benefits include eyeglasses, hearings aids, and additional drug coverage, as well as reduced out-of-pocket expenditures for covered services and reductions in expenditures for Medicare's Part B premiums (or Part D cost sharing in 2006).

Questions for the Honorable Mark B McClellan, M.D., Ph.D.
Administrator, Centers for Medicare & Medicaid Services
from the Honorable Charles Grassley,
Committee on Finance
regarding the September 14, 2004, hearing entitled
"Titles I and II: Features of the Proposed Regulations"

I have concerns about how regional Medicare Advantage plans are going to be setting up their networks in rural parts of the country. Many hospitals in Iowa have special payment status from Medicare and I want to make sure they are not going to be penalized when these health plans come in and try to negotiate contracts to set up their networks. In the Medicare Modernization Act, Congress gave specific authority to the Secretary to oversee these negotiations. I want to guarantee that our rural facilities won't be penalized in terms of reimbursements.

1. **The regulations propose relaxing the comprehensive network adequacy requirements for regional Medicare Advantage plans – why do you think that is necessary?**

Answer: As you know, CMS is committed to maximizing plan participation and choices for beneficiaries in rural states and those in urban states.

CMS recognizes that imposing network adequacy requirements is a delicate balance between protecting access for beneficiaries and affording organizations the flexibility they need to offer their plans. We have proposed to relax the comprehensive network adequacy requirements for MA regional plans, but only to the extent that beneficiaries are not put "at risk" for high cost sharing related to services received from non-network providers. We plan to use this flexibility in limited circumstances and not necessarily on a plan-wide basis. Specifically, this could be applied in a county or portion of a region where, for example, the MA regional plan is unable to secure contracts with an adequate number of a specific type of provider or providers to satisfy our comprehensive network adequacy requirements. CMS proposes to permit MA regional plans with lower out-of-network cost sharing to have less robust networks of contracted providers and vice-versa. This is because if the plans' networks were robust, we would not expect beneficiary access to be unduly limited by higher cost-sharing requirements when they seek care from out-of-network providers.

2. **How will you know that a health plan has made a "good faith effort" to contract with essential hospitals in rural areas?**

Answer: In our proposed rule we have asked for comments on how CMS can best ensure that a "good faith effort" has been made by a MA plan to contract with an essential hospital. For instance, we have asked whether we should require negotiations to occur before the admission of an MA regional plan patient to the essential hospital. Or, in the case of an emergency admission, we have asked if we should permit negotiations between the MA regional plan and the hospital to occur after admission, or perhaps even after discharge.

It's important to note that extra payments to essential hospitals will not be made available unless the hospital can demonstrate to CMS that its costs for providing care to a Medicare beneficiary exceed normal payment amounts. Additionally, CMS is asking for comments on how to determine these hospital costs.

3. Do you think that $25 million to help hold essential hospitals harmless will be sufficient for 2006?

Answer: The statute limits such payments to $25 million for 2006, and the prior year's amount to be updated by the market basket percentage increase for future years. Whether or not this amount will be sufficient depends on the number of hospitals who qualify as essential hospitals, how many beneficiaries they serve, and the difference between standard Medicare payments and the costs of the essential hospitals. Currently, we do not have sufficient data to accurately answer all of those questions, but with time we will be able to see whether the $25 million is enough.

Questions for the Honorable Mark B McClellan, M.D., Ph.D.
Administrator, Centers for Medicare & Medicaid Services
from the Honorable Max Baucus,
Commttee on Finance
regarding the September 14, 2004, hearing entitled
"Titles I and II: Features of the Proposed Regulations"

1. **The Medicare drug discount card has not met with the level of success that the administration intended. One of the reasons is that there are too many choices. Montana seniors can choose from among 41 options. The MMA gives CMS significant discretion to turn down PDP applicants – and specific reasons for doing so. Can you please comment on how you intend to use this authority? Under what conditions should drug plans be turned down from participating in the new Medicare Part D benefit?**

Answer: With the MMA, we now have the opportunity to take new steps to make the Medicare program more personalized, with more choices and better benefits for our seniors. The changes to the Medicare managed care program do exactly that – provide beneficiaries with the option to choose a plan that provides the best benefits for their needs.

This benefit is modeled after the FEHBP, where an individual can choose a plan based on factors such as health history, health status, and risk aversion. Just like the health insurance market for people under age 65, Medicare beneficiaries will now be able to choose the best plan for them.

The bottom line is that this is really an important step toward the future of Medicare – a Medicare that gives control back to patients to work with their doctors to get the benefits of personalized care, with the support of the Federal government to make good choices. It is extremely unlikely that beneficiaries will have to choose from as many options in any one location as they have in the case of drug cards. Still, we intend to provide information on beneficiary drug benefit options in many different forms that will allow beneficiaries to choose the best option for them.

In order for plans to participate, obviously, they will have to meet all of the qualifying criteria established under regulation. By accepting more than one plan, or multiple plans, for any given region, we will be promoting competition among those plans within the region they serve. This competition will drive prices down and will help both beneficiaries and the Federal government.

2. **CMS established the region size for the drug discount card to be no less than a state, but gave significant discretion to drug card participants to draw their own service areas. Now that CMS is considering region size for the 2006 drug benefit, I would like to recommend larger region sizes as one way to limit the number of potential participants. Would you agree that larger PDP regions is one way to limit the number of PDP plans, ensure that the options available represent the most qualified to participate, and guarantee that beneficiaries will not be inundated with too many choices?**

Answer: We have sought out and received comments from interested stakeholders on the appropriate number of PDP regions and will be seeking additional public comment again very shortly. In the comments we have received to date, we have heard from both those who would like smaller state-based regions and others who would prefer larger multi-state regions. We will be announcing a decision on the regions later this year – hopefully by the middle of the fall, though no later than January 1, 2005 as the statute requires.

The law directed CMS to conduct a market study and consider how different regional choices can maximize plan participation. CMS has hired a contractor – RTI International – to conduct that study, which is ongoing. CMS held a public meeting to present options for both sets of regions on Wednesday July 21, 2004 in Chicago, IL and has received scores of comments from potential PDP and MA plan bidders. It is our goal to establish regions that will result in sufficient plan participation to create competitive pressures to drive prices downward, while simultaneously providing beneficiaries with meaningful choice in how they obtain their care.

Dual Eligible and Low-Income Beneficiaries

3. **Dual eligible beneficiaries who fail to elect a drug plan will be automatically enrolled into a plan, and I support this decision. I understand that you have identified several options for how to achieve this policy goal. What factors will influence your decision to select an option? Will you consider the drugs that a dual eligible beneficiary is currently taking? And if not, how will you address the circumstance in which a dual eligible is assigned to a plan that does not cover a drug that he or she is currently taking?**

Answer: Full benefit dual-eligible individuals will be deemed eligible for the subsidy covering almost all of their drug costs. They will be given an opportunity to select a plan of their choice. If they do not select a plan, they will be automatically enrolled in a plan so that they do not lose these important benefits. Once enrolled, if the beneficiary finds that the plan does not cover a drug he or she is currently taking, the beneficiary may opt out and enroll in another plan without any penalty.

If there is a choice of more than one plan with a premium covered by the subsidy, the statute directs the Secretary to auto-enroll beneficiaries on a random basis.

Transitioning dual eligible beneficiaries to the new benefit is an important issue. We have been engaging states in discussions on transition issues because they will play an important role in educating dual eligibles about the upcoming changes impacting their drug coverage.

4. **Why did CMS decide not to automatically enroll Medicare Savings Programs beneficiaries into a drug plan, as it has proposed to do for the dual eligibles? What happens if these beneficiaries don't choose a plan, will they be subject to the late enrollment penalty if they fail to enroll during the open enrollment period?**

Answer: In the case of full dual eligible individuals, CMS was given a specific statutory directive to automatically assign these beneficiaries to a plan, should they fail to choose a plan on their own. The statute did not direct CMS to automatically enroll MSP beneficiaries into a plan. While MSP beneficiaries, who fail to enroll during the open enrollment period, will face late enrollment penalties if they choose to enroll at a later date, there are subsidies for late penalties for these beneficiaries.

5. **What steps will CMS take to make sure that low-income subsidy applicants are also screened for Medicaid and Medicare Savings Programs eligibility?**

Answer: We intend to be very aggressive about screening and enrolling applicants for any benefits to which they are entitled.

In addition to determining eligibility for premium and cost sharing subsidies for the new Medicare Part D prescription drug program, states are also required to determine eligibility for and offer enrollment into a Medicare cost-sharing program (QMB, SLMB, and QI) at the time they screen eligible individuals for low-income subsidies. We will be working with states to ensure that they understand their obligations with this requirement.

Furthermore, CMS will be working very closely with the Social Security Administration. SSA may advise people that, based on the fact that they have low income and resources, they may want to consider applying at the state Medicaid office for Medicare Savings Programs that provide assistance with Medicare premiums and, in some cases, cost sharing. SSA itself cannot take such enrollments as they are Medicaid functions. There is no affirmative obligation on SSA to screen and refer under MMA, as there is on states to screen and enroll, and in fact there may be issues related to privacy rights that limit the ability to share an applicant's personal information, but CMS will work to see if we can address these concerns.

However, concerned about low enrollment in Medicare savings programs generally, Congress passed legislation in 2000 requiring SSA to conduct outreach to low-income Medicare beneficiaries to notify them of their potential eligibility for Medicare savings programs. SSA began notifying beneficiaries in response to the statutory requirement in 2002.

6. **Determining initial eligibility for low-income subsidies is incredibly important, but so is the process of renewing eligibility. From other low-income programs, like Medicaid, we know that the renewal process, if not carefully designed, can result in**

the loss of eligibility of a huge proportion of enrolled individuals. The MMA requires that there be a renewal process of some sort at least once a year. The regulations do not describe that process. Please provide your current thinking on the issue of the renewal process.

Answer: For individuals who apply for the low-income subsidy, the initial period of eligibility is effective for a period not to exceed one year. Thereafter, the manner and frequency of re-determinations of eligibility will depend on which entity processed the initial determination; the state Medicaid office or SSA. If SSA processed the initial application, SSA will decide how often and in what manner re-determinations of subsidy eligibility are made. SSA is planning on issuing regulations, which will address its process. Since we expect that SSA will process most of the applications for the low-income subsidy, including many applications taken by states but forwarded to SSA for processing, SSA will likely be the responsible agency in most cases for individuals who apply for the subsidy.

State Medicaid agencies will re-determine subsidy eligibility for those beneficiaries whose applications have been processed by the state Medicaid agency. This is likely to occur in cases where individuals specifically request that the state, and not SSA, process the application for the subsidy. In such cases, the state will process the re-determinations in the same manner and frequency as they do under its Medicaid program, which must occur at least once every 12 months.

For the full benefit dual eligible population, who are deemed eligible for the Part D low-income subsidy, the renewal process will follow the normal Medicaid eligibility determination process. States will identify to CMS those eligible for Medicaid and thus automatically eligible for the subsidy by law. We are exploring options for individuals who tend to go on and off Medicaid eligibility, and hope to have more guidance in our final rule and other operational documents. Similarly, eligibility for MSPs would be re-determined under whatever schedule a state normally follows for its MSP groups regardless of whether an MSP-eligible person is receiving a low-income subsidy.

7. **What outreach and education efforts will CMS undertake to help states inform beneficiaries about the low-income subsidy? Is CMS considering a higher match rate for enrollment and outreach efforts?**

Answer: CMS and SSA are planning an aggressive outreach strategy for the low-income subsidy. SSA plans to mail applications to potential, non-deemed eligibles (those who are not full benefit dual eligibles or Medicare Savings Program beneficiaries) in early summer 2005 to encourage individuals who might be eligible to apply early for the low-income subsidy. In addition, SSA plans to educate community-based organizations, faith-based groups, state offices and employer groups about the low-income subsidy program, so that they can assist seniors with limited means in becoming aware of the program, and to encourage them or assist them directly in applying for the subsidy.

We also are working with State Medicaid Directors to develop strategies to educate dual eligible beneficiaries about the new Medicare prescription drug benefit, how this new program impacts

their coverage under Medicaid, and the process to enroll in prescription drug plans. However, state Medicaid programs will not receive a higher match rate for these activities. The statute only authorizes that states receive normal administrative match for low-income subsidy related activities.

We are also working with State Pharmaceutical Assistance Programs (SPAPs) to make sure we coordinate our outreach efforts with their enrollees. Under the MMA Congress set aside $125 million for FFYs 2005 and 2006 ($62.5 million each year) for grants to states with SPAPs to help them educate their enrollees about the Medicare drug benefit. CMS solicited applications from states in early July and received state applications in August. We are completing our review of these applications and will be informing states shortly about the results of their grant applications. We plan to make the funds for FFY 2005 available to states at the start of the fiscal year.

Medicare Advantage Program

8. I understand that private plans may be reluctant to participate as PPOs if the regions are defined too broadly. Are the health plans' concerns legitimate?

Answer: The goal of creating regional PPO plan options in Medicare Advantage is to maximize plan choices for beneficiaries. CMS wants to work with any plan that might be interested in becoming a regional PPO to encourage their participation to ensure access to these plans for all of our beneficiaries, including those living in rural areas. With regards to plan concerns over the size of a region, responses vary depending on the type of health plan. We have heard both sides -- some have said that they will participate if the regions are defined broadly and some have said that they will not. Having said that, it's important to note that several national plans have indicated to us that they will offer MA regional plans, regardless of the number of regions.

Through our outreach with a variety of plans, CMS has learned that several issues exist with defining large multi-state regions. These include a plan's ability to develop networks in a single state, let alone a multi-state region, especially in the compressed time frame. However, existing national plans with multi-state provider networks have stated that this is not a major concern. Another concern we have heard from state-based plans is that multi-state licensure is costly and burdensome for them. However, when drafting the law, Congress recognized that this would be an issue and included in the statute an exception. Specifically, although a plan must be licensed in at least one state within a multi-state region, they may be granted a waiver for licensure in the remaining states while licensure applications are pending. For plans that already have licenses in multiple contiguous states, this is not an issue.

9. If the regions are defined to be 50 states, won't PPOs cherry-pick the states, similar to how they cherry-pick counties today?

Answer: The regional plans required by the MMA must serve extensive geographic areas specified by CMS. Private plans cannot cherry pick counties, thus ensuring that areas not previously served by private plans in Medicare (particularly, rural counties) will have private, coordinated-care plan options available.

In addition, Congress has provided numerous incentives for plans to offer regional MA plans, regardless of region size. These include bonuses for plans to enter and remain in a region, as well as risk-sharing. These incentives should serve to make more Medicare Advantage options available to more Medicare beneficiaries, particularly in areas with no plans today. Specifically, incentives in the initial years of the program will be available to organizations that offer regional Medicare Advantage plans. These include risk-sharing arrangements between regional plans and CMS, as well as a $10 billion stabilization fund, which was established by the MMA to encourage regional plan participation.

We would expect regional PPOs to make a business decision whether to enter certain regional markets based on regional factors. These factors include population size, payment rates, existing provider networks, and existing commercial PPO participation. If a region does not have some or many of these factors, then it is conceivable that a prospective plan could reject that region in favor of other regions.

10. Plans have told me directly that they are not factoring in the "stabilization fund" in deciding whether or not to participate as a regional PPO. They believe the rules for accessing the fund are vague and subject to significant administrative discretion. Moreover, the fund, in my view, represents bad public policy. I believe it should be repealed next year in favor of more pressing priorities. Please share your views on what has become known as the "PPO slush fund."

Answer: Congress has authorized an MA Regional Plan Stabilization Fund in order to promote greater stability in the regional program and provide us with a tool to respond to market fluctuations. This is an important tool that will ensure options in all areas and opportunities for increased benefits and decreased costs for beneficiaries. It is true that regional PPOs may not need or receive any money from the stabilization fund. That decision will be made by the Secretary in response to how the market develops. The statute calls for the stabilization fund to be funded at $10 billion (plus additional amounts deposited into the fund when regional PPO plans bid below the benchmark) and to be available for eligible regional MA plans between January 1, 2007, and December 31, 2013.

The intent in making this additional funding available to regional MA plans is two-fold. First, it is intended to encourage managed care organizations to offer regional plans – a so-called entry bonus. Second, it is also intended to encourage managed care organizations to continue to offer regional plans –and has been called a plan retention bonus. Further, a bonus payment will be

made for any organization that offers a regional plan throughout the country in a single year. These bonus payments are structured similarly to earlier bonus payments made to Medicare+Choice organizations that were intended to reward plans that entered counties with no other private sector options.

11. For 2005, will risk adjustment be implemented on a budget-neutral basis, across all parts of the program as MedPAC has strongly recommended? If not, why not?

Answer: In light of the startup of the new Medicare Advantage program, CMS has decided to implement risk adjustment for 2005 in a budget neutral manner within the Medicare Advantage, as was done in 2004. Given that we are just now seeing growth in the program after several years of plans leaving and their benefits decreasing because of insufficient payments, we don't believe we should make policy changes at this point. For too long, payments to Medicare+Choice (M+C) plans have been inadequate, causing plans to pull out of the program and leaving seniors without a valuable option for receiving their Medicare benefits. The decision to risk adjust on a budget neutral basis in Medicare Advantage in addition to the new MMA plan funding in 2005 is also likely to bring additional Medicare Advantage plans into more markets serving Medicare beneficiaries, so that more beneficiaries have access to lower-cost, higher-benefit coverage options. At this point, we have not made any decisions about budget neutrality for future years.

12. Under the new competitive bidding system for private plans, which begins in 2006, does CMS intend to apply risk adjustment on a budget-neutral basis across all parts of the program as was intended by Congress?

Answer: The proposed Title II rule describes the various ways that risk adjustment would be used in the new competitive bidding methodology in order to ensure that plans are paid accurately for the health status of their members, so that plans with sicker beneficiaries are paid more than plans with healthier patients (in the same area). Likewise, if an MA plan enrolls healthy beneficiaries, it will be paid less than plans who enroll sicker beneficiaries, (in the same area).

In addition to risk adjusting the plan's payment for each enrollee, CMS will also risk adjust each plan's basic Part A/B bid and benchmark amounts to determine the amount of savings that will be returned to the government and beneficiary rebate dollars that will be returned to beneficiaries in additional benefits—the reduction of the Part B or Part D premiums, provision of non-Medicare covered benefits, and/or additional drug coverage.

CMS continues to refine risk adjustment methodology currently used to pay Medicare Advantage plans to improve its ability to provide higher payments for beneficiaries with complex conditions. A part of those refinements involves considering how to implement the risk adjustment measures in a budget neutral fashion. However, it's important to note that no decision has been made yet on the exact methodology.

13. During your confirmation hearing, you stated that CMS may be able to extract greater savings from health plans through aggressive implementation of the

competitive bidding provisions. Can you elaborate on steps CMS took in the Title II proposed rule to achieve greater efficiency and savings?

Answer: Our goal is to help plans achieve as much savings as possible so that plans can pass these savings onto beneficiaries in the form of more benefits and lower costs. CMS intends for the Medicare Advantage program to become a competitive, consumer-driven system that enables beneficiaries to join the plans best suited to their needs. This includes implementing the new Medicare Advantage program that strives to streamline the program and thereby reduce unnecessary plan costs while lowering costs for beneficiaries.

CMS has already undertaken a series of initiatives to reduce the unnecessary administrative burden faced by health plans during their participation in the M+C program. One example is modifying our standard contract with health plans to eliminate imposition of new, mid-year requirements, which were neither known nor built into rates when they were submitted to CMS.

We are committed to a transparent process and to educating plans on the new competitive bidding methodology and how to participate in the program. We are holding meetings not only to answer questions on the proposed rules, but also to solicit input on plan concerns regarding bidding in the new program. Another key component will be in providing information to beneficiaries on benefits through our website, hotline, and the "Medicare and You" handbook. Made available in a comparative form, this information increases transparency while continuing to drive down prices.

Fallback Plans

14. Please discuss the proposed criteria for selecting fallback plans? If fallback plans are selected based on the ability to secure discounts, shouldn't this criterion also be applied to at-risk plans?

Answer: I agree that the fallback provisions, which Sen. Baucus was instrumental in negotiating, are a crucial backstop to make sure that the prescription drug benefit is available to ***all*** Medicare beneficiaries on January 1, 2006. We are confident that with all the risk-sharing tools we have for the risk-bearing prescription drug plans (PDPs), that we will have a viable market with PDPs serving Medicare throughout the country. If, however, the market fails to work in any part of the country, we are committed to having a fallback contractor standing by to pay claims and provide drugs on schedule.

We are still developing our fallback contracting criteria, and we are very interested in receiving comments from potential bidders on how we can best structure the fallback contracts. The law directs us to run a competitive process, with plan payments tied to performance incentives, including cost containment and we are exploring ways to do that. We have retained the services of a consulting firm -- Booz Allen Hamilton – which has extensive experience in pharmacy benefit management contracting, and they are currently preparing a series of reports on our contracting issues for us. We expect to release more information as part of our bidding process in the coming months.

We expect that plans in all parts of the Medicare program will be working hard to secure discounts and low prices for prescription drugs, though the incentives to do so have different forms.

With fallback plans, we are working to develop performance metrics that will tie plan payments to cost containment, which necessarily includes drug prices. The specific metrics and payment incentives will be developed further as part of our bidding process, and we ask in the proposed rule for feedback on this point. We will be looking for potential fallback plans that can save money for both Medicare beneficiaries and the taxpayers by negotiating lower prices and using other formulary tools to drive cost-effective drug utilization.

For the at-risk plans, these tools are even more important, since they will be competing with one another to achieve low premiums for beneficiaries. Our actuaries and the Congressional Budget Office both agree that the at-risk plans will have significant incentives to drive hard bargains with manufacturers and use other formulary tools to encourage cost-effective utilization. Specifically, they project that over time, beneficiaries will migrate to the most cost-effective plans, increasing the discounts and other cost savings in the program.

USP Model Guidelines

15. Is the USP recommendation on therapeutic classification significantly different than the classes of drugs currently used by health plans in the private sector to establish formularies? If so, how?

Answer: It is our hope, and we have communicated this to US Pharmacopeia, that the model guidelines for drug classes and categories will reflect those currently used by pharmacy benefit managers and insurance plans. And we think the model guidelines issues last month are good step in that direction. Remember that plans are not required to use their guidelines. We want them to be useful and not sit on a shelf somewhere. We will monitor developments at USP as they work toward final guidelines.

16. Is there a need for CMS to seek a revision to the therapeutic class recommendations that were developed by the USP?

Answer: It is important to remember that CMS's review of the drug plans formularies' just begin with the categories and classes. Even more important are the drugs that are included on the list and what co-pay tiers those drugs are assigned to. Contrary to some of the rhetoric being thrown about, this is not a simple matter of checking for 2 drugs in each class. We intend to have a vigorous review process to make sure that a sufficient range of drugs is available to all Medicare beneficiaries and that vulnerable groups are not discriminated against in drug selection or through co-pays. In many cases – the AIDS drugs, for example -- I expect significantly more than 2 drugs will be required where they are available, since combinations of anti-viral medications are absolutely critical to keeping the virus at bay.

Our formulary review process will have to strike a balance between providing plans the flexibility they need to make discount deals with manufacturers and providing beneficiaries with guaranteed access to necessary medications. The USP guidelines are a piece of that process, but by far not the whole process.

Appeal Rights

17. **Dual eligible beneficiaries currently have due process rights for claims related to their Medicaid coverage. Some of these rights appear to be weakened by the proposed rule. For example, Constitutional and statutory "due process" now requires States to provide Medicaid beneficiaries with continued access to needed medical care while their appeal is pending – to make sure they are not left without access to a needed prescription pending a dispute with their plan. It doesn't appear to me that this standard is met by the proposed rule. Would you agree?**

Answer: All beneficiaries will have access to an appeals process through which they can request coverage for a non-formulary drug, or moving a drug from a high tier to a lower tier. An enrollee, or a prescribing physician on behalf of an enrollee, may file an exceptions request. Although neither are required to submit a physician's certification along with a request for an exception, nothing in the regulation would prohibit an enrollee, or his or her prescribing physician, from submitting a supporting physician's certification with the exceptions request. Plans are permitted to require a prescribing physician to submit a certification supporting the enrollee's exceptions request once a request has been submitted, and CMS expects that plans will routinely ask for them. Therefore, it would benefit enrollees to submit a physician's certification with his or her exceptions request, but they are not required to do so.

The statute requires plans to meet the requirements for plan-level appeals in the same manner as such requirements apply to benefits under the Medicare Advantage program. Thus, in the proposed rule, we adapted the Part C appeal procedures to Part D.

However, CMS does not believe that it has the statutory authority to require plans to provide continued coverage during the appeals process (continued access is not discussed in the MMA). Therefore, in the proposed rule CMS is attempting to resolve the issue by proposing to give PDPs a choice of either 1) providing enrollees with notice 60 days in advance of any formulary change and include information about how to obtain an exception and appeal in the notice, or 2) providing enrollees with a 60 day supply of a medication and notice of a formulary or tiering change when the change occurs. CMS also is proposing to shorten the adjudication timeframes so that it is possible to receive an Administrative Law Judge hearing within 7 days if necessary. Together, these proposals will ensure that enrollees will be able to obtain an independent review or switch to a medically appropriate alternative medication with little risk of coverage lapses.

18. **Although the new Medicare law gave the Secretary the authority to set standards for exceptions to the plan's formulary or cost-sharing rules, the proposed rule appears to delegate authority for establishing these standards to plans, and it appears the proposed rule would allow plans to require patients to meet a very tough standard in order to get an exception – requiring them to show medical and**

scientific evidence that the non-formulary drug is safer and more effective than the formulary one. Is this what you intended? It seems that under this scenario, plans would be able to apply a different standard to every patient seeking an exception. Would you agree?

Answer: We are proposing that plans have flexibility in designing their exceptions criteria but we will be working with plans to devise exceptions processes that are based on good medical evidence while being minimally burdensome to doctors, patients and pharmacists. Our review of plans includes making sure their exceptions process meets the standards specified in the final regulations. We certainly do not expect beneficiaries to review medical and scientific evidence in order to get a formulary exception.

We expect that Part D plans will have exceptions criteria that are fast and highly automated much like the market today. For example, we envision an exceptions process similar to Missouri's Medicaid program, which has a computerized system for its prior authorization restrictions. That state's program has the COX-2 inhibitors on prior authorization, since other pain relievers, such as aspirin or ibuprofen, are often just as safe and effective but at much less cost. If a beneficiary tries to fill a Celebrex prescription, the computerized prior authorization system works with the pharmacist to see if they patient meets any of the plan's scientifically established exceptions criteria. These include a prior history of gastrointestinal illness or concurrent use of a blood thinner such as warfarin, among others. If the patient meets the criteria, the coverage is automatically approved. If not, the patient's physician can still challenge the restriction with additional information by a phone-in process.

19. Please clarify what would happen in the following situation: an individual goes to their pharmacist for a prescription, but is told the prescription is not covered under the plan. Would the individual receive notice of the coverage decision and their right to appeal from the pharmacist? This seems like it will be a very common situation, so I am very interested in hearing how the appeal process will work and what information individuals will get so they will know their rights and be able to pursue an appeal.

Answer: CMS will make sure that beneficiaries are well informed of their appeal rights. PDP and MA-PD sponsors are required to give their enrollees written information about the grievance and appeal procedures available to them. We're asking for comments on this very important issue.

Current practice today when a drug is no longer covered by a plan is that the pharmacist informs individuals that their drug is no longer covered and instructs them to call their plan to appeal. We expect this practice apply in Part D. Under the proposed regulations an individual may file an appeal by either calling or writing to their plan. Should the plan deny the beneficiary's challenge, this becomes a coverage determination subject to several levels of appeal rights.

In general, the appeals system will follow the Medicare Advantage process, which includes access to independent reviews of plan decisions. Beneficiaries, prescribing physicians, or beneficiaries' authorized representatives can begin the appeals process, although only

beneficiaries or their authorized representative can appeal beyond the plan level. We would be happy to have any comments on how the appeals process should be structured and we certainly want it to be simple for the beneficiary to navigate.

Indian Health Service Pharmacies

20. I mentioned at the hearing that I am very concerned about access of Native American populations to IHS pharmacies. CMS has outlined two options in the proposed rule: (1) require all PDPs to contract with IHS and long term care pharmacies, or (2) strongly encourage all plans to contract with these pharmacies. It seems that there are drawbacks to both options. The drug discount card required that at least one card option be available to these vulnerable populations. Why not adopt this approach in the final rule?

Answer: The MMA gives the Secretary the option to include in the pharmacy access rules standards for pharmacies operated by the Indian Health Service (IHS), Indian tribes and tribal organizations, and urban Indian organizations (I/T/Us) in the access rules. This provision gives us necessary flexibility to decide how best to achieve the access goals for Indian beneficiaries.

Our proposed rules sought comments on two alternatives:
(1) A requirement for all drug plans to include I/T/U pharmacies, or (2) strong encouragement for plans to include them. In the preamble of the proposed rule, we discuss the pros and cons of each alternative for each of these specialized pharmacies.

We explained two concerns with these alternatives: (1) that requiring *all* plans to contract with such pharmacies may be unduly burdensome, given the special accommodations that are likely to be necessary, but (2) even strong encouragement and assistance may not be successful in persuading *enough* plans to include these pharmacies. That is why we did not make a decision on these matters but sought comments on them through the NPRM. We are considering the comments we have received.

Quality and Pay for Performance

21. I recently introduced a bill (S. 2562) to initiate a pay-for-performance policy for the ESRD and Medicare Advantage programs. The bill is based on recommendations by MedPAC, and I believe it lays out a path for incorporating quality into Medicare payment systems for the future. CMS may not be able to take a position on pending legislation, but I would appreciate if you could share your views on how Medicare can move forward and play a leading role in the health care quality debate. How can quality-related provisions in the MMA, such as Section 501, which tied hospital payments to reporting data on ten quality indicators, inform Medicare's progress along this path?

Answer: The Centers for Medicare & Medicaid Services (CMS) has been active in promoting pay for performance, with several activities underway or in development that use financial incentives for quality improvement, including the Premier Hospital Quality Incentive

demonstration, the Physician Group Practice Management demonstration, the ESRD Disease Management demonstration, the Medicare Care Management Performance demonstration, and the Medicare Health Care Quality demonstrations.

In July 2003, we launched the first Medicare demonstration project that uses financial incentives to encourage hospitals to provide high quality inpatient care. The Premier Hospital Quality Incentive demonstration rewards hospitals with higher Medicare payments when they deliver the best quality care. It involves a CMS partnership with Premier Inc., a nationwide organization of not-for-profit hospitals. Through this demonstration, CMS aims to see a significant improvement in the quality of inpatient care by awarding bonus payments to hospitals for high quality in several clinical areas, and by reporting extensive quality data on the CMS web site.

Further, as you mentioned above, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) propelled pay for performance forward. For the first time in the history of the Medicare program, Medicare payment was linked to the submission of quality data under section 501 of the MMA. Nearly all of the nation's eligible hospitals have begun reporting data on the quality of care they deliver, which is a vital step in improving patient care. Hospitals that submit quality information to CMS will be eligible to receive the full Medicare payment for health care services in 2005. Although reporting is voluntary, those inpatient acute care hospitals that do not report will get a 0.4 percentage point reduction in their annual Medicare update. This provides a strong financial incentive for eligible hospitals to submit data for the 10 quality measures. These results provide strong evidence that when it comes to quality reporting, payment incentives are nearly 100 percent effective. In turn, quality information will provide further incentives to improve the quality of care available to millions of Americans as patients and doctors start using this quality information to help them make decisions about hospital care.

In addition, the Medicare Care Management Performance demonstration, authorized by section 649 of the MMA, is under development. In this demonstration, Medicare will establish a pay for performance 3-year pilot with physicians to promote the adoption and use of health information technology to improve quality and reduce avoidable hospitalizations for chronically ill patients. Doctors who meet or exceed performance standards (set by CMS) will receive a bonus payment for managing the care of eligible Medicare beneficiaries. The pilot must show that it does not cost Medicare more than the program would have spent on the beneficiary otherwise.

Linking quality performance to payment is where health care is heading in the future. While we build on our pay for performance efforts, we also recognize the importance of expanding the information available about quality of care through the Department's ongoing Quality Initiative. In November 2001, Secretary Tommy G. Thompson announced the Quality Initiative and his commitment to assure quality health care for all Americans through published consumer information. The Quality Initiative was launched nationally with the Nursing Home Quality Initiative (NHQI) and expanded in 2003 with the Home Health Quality Initiative (HHQI) and the Hospital Quality Initiative (HQI). These initiatives are part of a comprehensive look at quality of care that now also includes the Doctor's Office Quality (DOQ) project and End-Stage Renal Disease quality projects.

Questions for the Honorable Mark B McClellan, M.D., Ph.D.
Administrator, Centers for Medicare & Medicaid Services
from the Honorable Jeff Bingaman,
Committee on Finance
regarding the September 14, 2004, hearing entitled
"Titles I and II: Features of the Proposed Regulations"

1. **Auto-Enrollment in the Drug Card: I remain concerned about the Discount Card, which has not gotten off the ground or seen much success. One option remains to auto-enroll low-income Medicare Savings Program beneficiaries into the program in order to receive the $600 annual subsidy. Months ago, you testified before this committee that "auto-enrollment is one way to increase the number of people who take advantage of the program." Why has CMS failed to do so and thereby left hundreds of thousands of eligible low-income seniors and people with disabilities without the $600 subsidy?**

Answer: I am pleased to inform you that we are making progress in establishing a method to ensure that MSP beneficiaries are enrolled in the Medicare-Approved Drug Discount Card and Transitional Assistance Program. CMS has been diligently evaluating options as to how to assist in the enrollment of the MSP population. In the past few months, CMS has conducted an extensive review of its legal authority, including a proposal submitted by the ABC Coalition, a group of non-profit organizations that has come together to assist low income beneficiaries find prescription drug savings programs. In addition we have had extensive discussions with states and drug card sponsors regarding a process to auto-enroll MSP beneficiaries.

Under this approach, each MSP beneficiary will be randomly assigned a card and will be sent that card along with a letter instructing the beneficiary that they may also be eligible for the $600 credit. The beneficiary will have the opportunity to opt out if he or she does not want the assigned card, and will be allowed to choose another card within a given time frame.

In order to receive the $600 credit, the beneficiary will need to call either the drug card sponsor or 1-800-MEDICARE and attest that they do not have other prescription drug coverage.

While MSP beneficiaries are deemed income eligible, we need further clarification for purposes of determining which coinsurance group the beneficiary should be assigned. Therefore, the beneficiary will need to provide information about their income so that we can assess which coinsurance amount they will pay -- 5% or 10%-- per prescription when using the $600 credit. Once the attestation is made, the beneficiary will be enrolled in the Transitional Assistance and will be able to use the $600 toward their drug expenses effective the first day of the month following their attestation. Enrollment in the card will be effective November 1, 2004. They will also automatically be eligible for the $600 in 2005.

2. **Implementation of Payments to Providers for Emergency Care to Undocumented Immigrants: I have spoken and written to you in the past about the need to ensure that CMS implements the $250 million in payments to emergency care providers who deliver care to undocumented immigrants (Section 1011 of MMA) is done is a**

manner that is not overly bureaucratic or burdensome to health care providers and does not lead to fear and intimidation in the immigrant community, which could spark a public health crisis. Unfortunately, that is precisely what I believe will happen as a result of the "policy paper" that CMS has issued as guidance for providers to be reimbursed under this section of the law. Hospital, immigrant, and Hispanic community advocates have all recommended a number of alternatives to trying to "document the undocumented", which by definition makes no sense, by using proxies and other mechanisms to receive reimbursement. Have those alternatives been rejected and, if so, why?

Answer: CMS proposed an approach to implement section 1011 and solicited public comment. We are currently analyzing the public comments submitted and are working to finalize an implementation plan, which we hope to publish shortly.

Section 1867 of the Social Security Act (EMTALA) requires a hospital that provides emergency services to medically screen all persons who come to the hospital seeking emergency care to determine whether an emergency medical condition exists. The proposed process under section 1011 is consistent with this EMTALA requirement and would not allow a delay in the medical screening examination because of inquiries about citizenship.

There is nothing in the proposed process that is different than is currently being done right now. After the medical screening examination and after basic treatment is provided, the hospital can ask the individual how payment will be made—through Medicare, Medicaid, or private insurance, if any.

We received a number of comments on the documentation requirements included in our proposal. We are carefully reviewing these comments to see if there are ways to ease the burden on hospitals, while fulfilling our fiduciary responsibility to the Medicare Trust Fund.

Section 1011 of the MMA provides $250 million per year for fiscal years (FY) 2005-2008 for payments to eligible providers for emergency health services provided to undocumented aliens and other specified aliens.

Two-thirds ($167 million) will be allotted in all 50 states and the District of Columbia, based on their relative percentages of the total number of undocumented aliens. The remaining one-third ($83 million) will be allotted to the six states with the largest number of undocumented alien apprehensions for such fiscal year (AZ, CA, FL, NM, NY, and TX).

On July 22, 2004, CMS issued a proposed implementation plan for section 1011. One aspect of the plan was to require hospitals to ask patients about their citizenship status in order to receive reimbursement under section 1011.

Questions about citizenship status are currently used for purposes of Medicaid eligibility. To apply for Medicaid, an applicant must declare that he or she is a citizen or national of the United States or an alien in a satisfactory immigration status. Under the proposed process for section 1011, the individual can decline to answer this question.

3. **Auto-Enrollment in the Drug Plans in 2006: Once again, why not automatically enroll beneficiaries in Medicare Savings Programs into a drug plan in 2006, as you have proposed to do for the dual eligibles? What happens if these beneficiaries don't choose a plan? Will they be subject to the late enrollment penalty?**

Answer: In the case of full dual eligible individuals, CMS was given a specific statutory directive to automatically assign these beneficiaries to a plan, should they fail to choose a plan on their own. The statute did not direct CMS to automatically enroll MSP beneficiaries into a plan. While MSP beneficiaries, who fail to enroll during the open enrollment period, will face late enrollment penalties if they choose to enroll at a later date, there are subsidies for late penalties for these beneficiaries.

4. **CMS Overpayments to Health Plans: It appears that CMS has not followed MedPAC's recommendation for implementation of risk-adjustment. For 2005, will risk adjustment be implemented on a budget-neutral basis among just health plans or across all parts of the program as MedPAC has strongly recommended? If not, why and what is the estimated cost of that policy to Medicare?**

Answer: In light of the startup of the new Medicare Advantage program, CMS has decided to implement risk adjustment for 2005 in a budget neutral manner within the Medicare Advantage program. The decision to risk adjust on a budget neutral basis in addition to the new MMA plan funding in 2005, that was announced in May 2004, is also likely to bring additional Medicare Advantage plans into more markets serving more Medicare beneficiaries, so that more beneficiaries have access to lower-cost, higher-benefit coverage options. With these changes, we are now seeing a return to a stable managed care program. For too long, payments to Medicare+Choice (M+C) plans have been inadequate, causing plans to pull out of the program and leaving seniors without a valuable option for receiving their Medicare benefits. At this point, we have not made any decisions about budget neutrality for future years.

5. **Ensuring Dual Eligibles Receive Appropriate Access to Drugs: Almost all states have recognized the unique needs of individuals with mental illness and provided exemptions for mental health medications including antipsychotics and antidepressants while employing cost-saving techniques. Physicians are currently able to prescribe medicines to their dual eligible, special-needs populations. When passing the MMA, Congress did not intend to diminish benefits for dual eligible beneficiaries with mental illnesses. After January 1, 2006, how will CMS, in its regulations, ensure continuity of care and access to necessary treatment for these special needs patients?**

Answer: CMS will not allow plans to place arbitrary limits on the number of prescriptions that beneficiaries may fill. The drug benefit is an open-ended entitlement, featuring catastrophic coverage with no upper limit. If a physician prescribes multiple medications for a beneficiary, all are eligible for coverage under the terms of the plan. The MMA establishes special enrollment periods which will permit dual eligible beneficiaries to change plans if their medications aren't covered. CMS will work to make this clear in the final rule and in

forthcoming sub-regulatory guidance. However, plans will have authority to combat waste and fraud by placing reasonable limits on the quantity of medicine dispensed or the frequency of refills, but they cannot, for example, limit the total number of prescriptions filled per month as certain state Medicaid programs do.

All beneficiaries will have access to an appeals process through which they can request coverage for a non-formulary drug, or moving a drug from a high tier to a lower tier. An enrollee, or a prescribing physician on behalf of an enrollee, may file an exceptions request. Although neither are required to submit a physician's certification along with a request for an exception, nothing in the regulation would prohibit an enrollee, or his or her prescribing physician, from submitting a supporting physician's certification with the exceptions request. Plans are permitted to require a prescribing physician to submit a certification supporting the enrollee's exceptions request once a request has been submitted, and CMS expects that plans will routinely ask for them. Therefore, it would benefit enrollees to submit a physician's certification with his or her exceptions request, but they are not required to do so.

CMS will review plan formularies to ensure that Part D plans offer a comprehensive benefit that does not discriminate against beneficiaries with a particular disease or condition, including dual eligibles. In addition, we will review plan administrative control requirements and appeals processes to ensure that vulnerable beneficiaries will have appropriate access to the medications they require.

6. **Ensuring Dual Eligibles Are Not Worse Off Than Under Medicaid: Although those dual eligible beneficiaries who do not participate in the enrollment process for the prescription drug benefit will be automatically enrolled in the Medicare Part D benefit, how will CMS ensure that those dual eligible beneficiaries who are automatically enrolled in a prescription drug plan maintain the same benefits they received under Medicaid?**

Answer: CMS will not allow plans to place arbitrary limits on the number of prescriptions that beneficiaries may fill. The drug benefit is an open-ended entitlement, featuring catastrophic coverage with no upper limit. If a physician prescribes multiple medications for a beneficiary, all are eligible for coverage under the terms of the plan. The MMA establishes special enrollment periods which will permit dual eligible beneficiaries to change plans if their medications aren't covered. CMS will work to make this clear in the final rule and in forthcoming sub-regulatory guidance. However, plans will have authority to combat waste and fraud by placing reasonable limits on the quantity of medicine dispensed or the frequency of refills, but they cannot, for example, limit the total number of prescriptions filled per month as certain state Medicaid programs do.

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7. **Dual Eligibles' Appeals Rights: Dual eligible beneficiaries currently have due process rights for claims related to their Medicaid coverage. Some of these rights appear to be weakened by the proposed rule. For example, Congress intended that Medicaid beneficiaries have the right to continued access to needed medical care while their appeal is pending – to make sure they are not left without access to a needed prescription pending a dispute with their plan. It doesn't appear to me that this standard is met by the proposed rule. What steps are you taking to ensure protections for these vulnerable citizens?**

Answer: All beneficiaries will have access to an appeals process through which they can request coverage for a non-formulary drug, or moving a drug from a high tier to a lower tier. An enrollee, or a prescribing physician on behalf of an enrollee, may file an exceptions request. Although neither is required to submit a physician's certification along with a request for an exception, nothing in the regulation would prohibit an enrollee, or his or her prescribing physician, from submitting a supporting physician's certification with the exceptions request. Plans are permitted to require a prescribing physician to submit a certification supporting the enrollee's exceptions request once a request has been submitted, and CMS expects that plans will routinely ask for them. Therefore, it would benefit enrollees to submit a physician's certification with his or her exceptions request, but they are not required to do so.

The statute requires plans to meet the requirements for plan-level appeals in the same manner as such requirements apply to benefits under the Medicare Advantage program. Thus, in the proposed rule, we adapted the Part C appeal procedures to Part D.

However, CMS does not believe that it has the statutory authority to require plans to provide continued coverage during the appeals process (continued access is not discussed in the MMA). Therefore, in the proposed rule CMS is attempting to resolve the issue by proposing to give PDPs a choice of either 1) providing enrollees with notice 60 days in advance of any formulary change and include information about how to obtain an exception and appeal in the notice, or 2) providing enrollees with a 60 day supply of a medication and notice of a formulary or tiering change when the change occurs. CMS also is proposing to shorten the adjudication timeframes so that it is possible to receive an Administrative Law Judge hearing within 7 days if necessary. Together, these proposals will ensure that enrollees will be able to obtain an independent review or switch to a medically appropriate alternative medication with little risk of coverage lapses.

Questions for the Honorable Mark B McClellan, M.D., Ph.D.
Administrator, Centers for Medicare & Medicaid Services
from the Honorable John Breaux,
Committee on Finance
regarding the September 14, 2004, hearing entitled
"Titles I and II: Features of the Proposed Regulations"

1. **One provision of the MMA that has received a great deal of attention has been the "noninteference" provision which states that the Secretary "(1) may not interfere with the negotiations between drug manufacturers and pharmacies and PDP sponsors; and (2) may not require a particular formulary or institute a price structure for the reimbursement of covered part D drugs." I, for one, have stated in the past that I don't believe this provision has a significant effect on drug prices because the drug benefit under this law is provided by private plans. If we were to strike this provision, I don't believe that the Secretary could or would negotiate drug prices on behalf of the private companies offering these plans. CBO seems to agree and has stated that "substantial savings will be obtained by the private plans and that the Secretary would not be able to negotiate prices that further reduce federal spending to a significant degree." However, that said, some members have criticized the provision despite the fact that it has been in numerous other bipartisan bills in the past. Could you explain the effect of this provision and why the Administration believes that the best method to achieve lower drug prices is for the private plans administering the drug benefit to negotiate those prices themselves? Why is this method preferred to what the VA does when it sets drug prices or what the state Medicaid programs do when they bargain for drug prices?**

Answer: Both the Congressional Budget Office and the actuaries at CMS agree that plans under Medicare's new drug benefit will achieve significant cost management savings, including lower prices, by negotiating with drug makers and applying a range of utilization management tools. CBO predicts this cost management factor will achieve 20 percent savings in 2006, rising to 25 percent over time as beneficiaries gain experience with plans and migrate to more efficient plans with lower drug prices and premium. The CMS Office of the Actuary prediction is similar, 15 percent in 2006 rising to 25 percent over time. Prescription drug plans and Medicare Advantage plans will have strong incentives to negotiate good drug prices and otherwise control costs, as they will carry insurance risk for the drug benefit. With these strong incentives in place, interference from the Secretary in the negotiation is not expected to reduce prices.

The MMA relies on these market incentives to bring down drug prices. Medicare's history with direct price setting is not one to be proud of. For years, Medicare clearly overpaid for Part B drugs for years using the AWP methodology, and these overpayments are just now being corrected as part of the MMA changes. Some have suggested that Medicare should link to the prices received by the Veterans Administration, but this would not lower Medicare prices. Rather, it would raise VA prices. The VA is about a 2 percent market player, whereas Medicare beneficiaries together are expected to account for 40 percent of total drug spending. If the two were linked, manufacturers' strategic response would be to raise prices on the small fry. That is

why the MMA explicitly de-links drug prices between Medicare and Medicaid to prevent these kind of unintended consequences from occurring.

2. **It's very important, especially for the dual eligibles who are switching from Medicaid prescription drug coverage (which is extremely generous) to Medicare coverage, that beneficiaries have the right to appeal if the drug their doctor prescribes is not on their plan's formulary or if it is covered only at a high level of cost-sharing. It seems that CMS has left this appeals process or exception process largely up to the plans – with each plan setting its own process. It's vital that this process be navigable for seniors, especially for those with chronic conditions, those who are low-income, and those taking a number of prescription drugs. It should not be too confusing, and seniors should not have to submit too much documentation (for example, having to gather scientific journal articles proving the superiority of the drug for which they are requesting coverage.) As I've said many times, I think this program combines "the best of what the government can do with the best of what the private sector can do" – this is a perfect instance of something that the government (CMS) should do – that is give more guidance on and provide oversight to ensure that seniors can get the drugs they need. Will CMS provide more guidance in the final rule on this issue? Can you please describe the extent to which CMS will give plans direction in designing their exceptions processes?**

Answer: All beneficiaries will have access to an appeals process through which they can request coverage for a non-formulary drug, or moving a drug from a high tier to a lower tier. An enrollee, or a prescribing physician on behalf of an enrollee, may file an exceptions request. Although neither are required to submit a physician's certification along with a request for an exception, nothing in the regulation would prohibit an enrollee, or his or her prescribing physician, from submitting a supporting physician's certification with the exceptions request. Plans are permitted to require a prescribing physician to submit a certification supporting the enrollee's exceptions request once a request has been submitted, and CMS expects that plans will routinely ask for them. Therefore, it would benefit enrollees to submit a physician's certification with his or her exceptions request, but they are not required to do so.

However, we do not believe that we have the statutory authority to require plans to provide continued coverage during the appeals process (continued access is not discussed in the MMA). Therefore, in the proposed rule we are attempting to resolve the issue by proposing to give PDPs a choice of either 1) providing enrollees with notice 60 days in advance of any formulary change and include information about how to obtain an exception and appeal in the notice, or 2) providing enrollees with a 60 day supply of a medication and notice of a formulary or tiering change when the change occurs. We also are proposing to shorten the adjudication timeframes so that it is possible to receive an Administrative Law Judge hearing within 7 days if necessary. Together, these proposals will ensure that enrollees will be able to obtain an independent review or switch to a medically appropriate alternative medication with little risk of coverage lapses.

We certainly aren't going to require beneficiaries to go out and read medical journals in order to get a formulary exception. We will work with plans to devise exceptions processes that are

based on good medical evidence while being minimally burdensome to doctors, patients and pharmacists.

In the market today, many of these exceptions criteria are highly automated and very quick. Missouri's Medicaid program has a computerized system for its prior authorization restrictions. That state's program has COX-2 inhibitors on prior authorization, because other pain relievers, such as aspirin or ibuprofen, are often just as safe and effective but at much less cost. If a beneficiary tries to fill a Celebrex prescription, the computerized prior authorization system works with the pharmacist to see if they patient meets any of the plan's scientifically established exceptions criteria. These include a prior history of gastrointestinal illness or concurrent use of a blood thinner such as warfarin, among others. If the patient meets the criteria, the coverage is automatically approved. If not, the patient's physician can still challenge the restriction with additional information by a phone in process, and the state has worked to get call times down to a minimum.

3. **The MMA required that the Secretary request the United States Pharmacopeia (USP) to produce a "model formulary" which, if plans adopt, will satisfy the plans' nondiscrimination requirement. It is therefore vital that this model formulary be truly nondiscriminatory and that its design not include widely used drugs, especially newer, more advanced drugs. While I appreciate that an overly inclusive formulary could lead to much higher drug expenditures, I also feel that access to clinically appropriate medications is vitally important, especially for beneficiaries with low incomes and/or chronic health problems.**

   I have heard concerns that the USP's current draft formulary could allow PDPs to exclude coverage of certain widely used drugs, including statins and SSRIs. Is this correct? And if so, what specific actions does CMS plan to take to ensure that these drugs are available to beneficiaries?

Answer: Medicare will provide seniors with coverage for the medicines they need at the lowest possible price when the new Medicare prescription drug benefit begins in 2006. It makes no sense to create a new prescription drug program that does not cover the drugs seniors take. It is critical to note that by law, the drug benefit must not discriminate against the needs of Medicare beneficiaries, regardless of their health problems. Also, the process to develop clear guidance to prescription drug plans will be public and will examine all aspects of a drug benefit. The Medicare drug benefit will be a *comprehensive* benefit, covering an amount and a variety of drugs sufficient to treat all diseases. The benefit will save seniors who currently lack good drug coverage hundreds or even thousands of dollars a year, while giving them access to high-quality medicines. CMS has the authority it needs to review and approve plan formularies, as well as the authority to negotiate with plans on these and other benefit design features. The agency will use this authority to ensure that beneficiaries get the drugs they need at the lowest possible cost.

The USP model guidelines will be a valuable piece of CMS's formulary review process, but is only one piece of a much bigger pie. In addition to the categories and classes, CMS will review the actual drugs chosen to populate the formulary, the co-pays assigned to the drugs, the exceptions and prior authorization rules, as well as the appeals process. Only when viewing all

these pieces together, can one make a judgment about beneficiary access to needed medicines. Two drugs per class is not a hard and fast rule – just a minimum floor. In many cases – AIDS drugs, for example -- I expect significantly more than 2 drugs will be required where they are available, since combinations of anti-viral medications are absolutely critical to keeping the virus at bay.

Our formulary review process will have to strike a balance between providing plans the flexibility they need to make discount deals with manufacturers and providing beneficiaries with guaranteed access to necessary medications. The USP guidelines are a piece of that process, but by far not the whole process.

Questions for the Honorable Mark B McClellan, M.D., Ph.D.
Administrator, Centers for Medicare & Medicaid Services
from the Honorable Tom Daschle,
Committee on Finance
regarding the September 14, 2004, hearing entitled
"Titles I and II: Features of the Proposed Regulations"

1. **The proposed rule allows private drug plans to exclude Indian Health Service pharmacies from their networks. Was that an oversight? If so, do you plan to correct it in the final rule? If not, how do you justify excluding those facilities? Can you explain why the proposed rule does not appear to provide appeal rights for beneficiaries who use a non-network pharmacy?**

Answer: The MMA gives the Secretary the option to include in the pharmacy access rules standards for pharmacies operated by the Indian Health Service (IHS), Indian tribes and tribal organizations, and urban Indian organizations (I/T/Us) in the access rules. This provision gives us necessary flexibility to decide how best to achieve the access goals for Indian beneficiaries.

Our proposed rules sought comments on two alternatives:
(1) A requirement for all drug plans to include I/T/U pharmacies, or (2) strong encouragement for plans to include them. In the preamble of the proposed rule, we discuss the pros and cons of each alternative for each of these specialized pharmacies.

We explained two concerns with these alternatives: (1) that requiring *all* plans to contract with such pharmacies may be unduly burdensome, given the special accommodations that are likely to be necessary, but (2) even strong encouragement and assistance may not be successful in persuading *enough* plans to include these pharmacies. That is why we did not make a decision on these matters but sought comments on them through the NPRM. We are considering the comments we have received.

2. **What sort of efforts have you made to educate beneficiaries who live on reservations about the drug card and the drug benefit? What do you have planned?**

Answer: On a general level, CMS has mailed information to all Medicare beneficiaries concerning the drug discount card. The Agency has run print and broadcast advertising in both English and Spanish in order to make beneficiaries and their caregivers aware of this important new program. CMS staff has engaged in literally hundreds of outreach events around the country as well. CMS is also partnering with community-based organizations, states, and other federal agencies to outreach to beneficiaries about the drug card.

In addition, we have made a number of special efforts to educate Indian Medicare beneficiaries and the IHS, Tribal, and urban Indian health programs (I/T/Us) that serve them both on and off the reservations about the drug card. The special drug discount card educational efforts were accomplished in several ways. CMS conducted an Open Door Forum on Indian issues and the drug discount card on May 17, 2004. CMS also used the satellite broadcast network that links to

more than 50 IHS and Tribal health programs to conduct a live broadcast with call-in questions and answers on May 28, 2004. CMS entered into an inter-agency agreement with IHS and conducted training sessions in September and October 2004 in each of the 12 IHS Areas for patient benefits coordinators and staff from tribal and urban health programs who have direct contact with beneficiaries. The training packages prepared for these sessions contained a variety of materials for future reference, including staff fact sheets, a training diskette with additional information on the program, and informational posters for display in patient access areas of Indian hospitals, clinics, and pharmacies. The two specially endorsed drug card sponsors that offer drug discount cards tailored for I/T/Us and their beneficiaries respond to questions from I/T/Us and beneficiaries on an ongoing basis. Tribal representatives have been pleased with the training approach used for the drug card. The CMS inter-agency agreement with IHS includes funding to develop additional outreach materials for the drug discount card to be used in 2005. We are considering use of similar techniques to those used for the drug discount card for providing Indian-specific information on the Part D drug benefit.

In FY 04, SHIP funding will total $21,062,500. This amount consists of $13.5 million in basic funding, $1,562,500 additional funding to help the SHIPs prepare for activity related to the Medicare-approved Prescription Drug Card, and $6 million additional funding to help them prepare for activities related to the Drug Card and the upcoming Part D Prescription Drug Benefit.

In FY 05, SHIP funding will be $31,675,000. This will include $14,175,000 in basic funding, $2,500,000 to assist SHIPs with Prescription Drug Card related activity, and $15,000,000 for activities related to the Part D Prescription Drug benefit.

CMS has also awarded a $4.16 million task order to Ogilvy PR Worldwide for the purpose of organizing and funding community-based organizations (CBOs) to help low-income Medicare beneficiaries learn about Medicare-approved discount drug cards and how to enroll in the program.

CMS is partnering with leading non-profit organizations, such as Access to Benefits Coalition, to educate low-income beneficiaries on the drug card program. The Coalition's objective is to enroll at least 5.5 million low-income beneficiaries for the $600 credit by the end of 2005. With the support of the Administration on Aging the funding for this task has been increased by another 1.75 million. The focus of this effort is to identify at least 200 CBOs that can conduct outreach activities in the top 30 markets; these top 30 markets target the locations where approximately 70 percent of the low-income beneficiaries reside.

3. **How much money has the Centers for Medicare and Medicaid Services (CMS) and the Department of Health and Human Services (HHS) spent on advertisements (print, television, mailings) promoting or otherwise notifying the public about the new law? How much have you spent targeting Native American communities to let them know how to enroll in the cards?**

Answer: There were two waves of advertising for the drug card this year for the Spring totaling about $32.9 million and for the Summer totaling about $17.2 million. Also, $4.6 million for

community based organizations and $21.1 million this year and $31.7 million next year for State Health Insurance Assistance Programs to outreach, educate and enroll beneficiaries about the drug card. Additionally, CMS and Administration on Aging awarded $3.7 million to grassroots organizations for their drug card outreach efforts.

Special drug cards will be available for American Indians and Alaskan Natives at Indian heath program pharmacies on October 8th. CMS and Indian Health Service are working in partnership on outreach, education and enrollment of the special drug cards. HHS has spent a total of $224,000 on training and outreach materials and posters targeting the American Indians and Alaskan Natives communities. CMS will continue outreach efforts to this community to ensure all who qualify for the special drug cards and for the $600 credit enrolls.

4. How much money have CMS and HHS spent to promote public awareness of the Medicare oral anti-cancer and self-injectible demonstration projects? Have you made any efforts to target rural beneficiaries? Why is enrollment in the program so low? How do you plan to meet the enrollment level of 50,000 people?

Answer: Our goal is to make sure that all beneficiaries who can benefit from this demonstration projects are aware of it and make the choice to apply. The outreach has been targeted to those beneficiaries who can benefit from this project who have serious diseases such as cancer, multiple sclerosis, and rheumatoid arthritis. Those who enroll in the project can receive savings up to 90 percent on the cost of oral and self-injectable drugs that replaces previously only delivered in physician offices.

We have conducted various outreach activities at the local level working with CMS regional offices and SHIPs. We have also worked with key advocacy organizations, disease groups, health plans and drug store groups to reach out to beneficiaries who use the covered drugs. In addition, some MA plans that offer limited drug benefits have sent targeted letters to eligible beneficiaries in their plans. We are encouraging PDP plans to do the same sort of outreach.

Information about the demonstration also comes up on CMS Price Compare website when a beneficiary indicates they are taking one of the demonstration's covered drugs.

In addition, we had an article in the September 12th issue of Parade Magazine (Sunday newspaper supplement). Also this past week, special pharmacy newsletters started printing out in selected pharmacies (approximately one-third of pharmacies) across the country when beneficiaries fill a prescription for one of the demonstration's covered drugs. The newsletter includes information about the demonstration and how to apply.

When the September 30th enrollment deadline passes and the 50,000 beneficiaries limit has not been reached then we will have a "rolling" enrollment period until we reach the limit.

It is difficult to quantify the amount specifically used for outreach because it primarily involves staff time presenting at meetings and corresponding with interested groups. We are spending approximately $100,000 through Trailblazer for the special pharmacy newsletters print out when beneficiaries fill a prescription for one of the demonstration's covered drug.

5. **Several patient groups have raised concerns that the US Pharmacopeia Draft Model Guidelines would allow plans to exclude certain important drugs such as SSRIs or statins from their formularies. Given the statute's provision limiting the Secretary's ability to review the formularies if they comply with the Guidelines, how will you ensure that such critical drugs are covered by the plans? Are the Draft Model Guidelines' definition of each pharmacologic class appropriate? Are these classes broad enough that plans will be able to use the formularies to discourage beneficiaries with certain conditions from enrolling?**

Answer: Medicare will provide seniors with coverage for the medicines they need at the lowest possible price when the new Medicare prescription drug benefit begins in 2006. It makes no sense to create a new prescription drug program that does not cover the drugs seniors take. It is critical to note that by law, the drug benefit must not discriminate against the needs of Medicare beneficiaries, regardless of their health problems. Also, the process to develop clear guidance to prescription drug plans will be public and will examine all aspects of a drug benefit. The Medicare drug benefit will be a *comprehensive* benefit, covering an amount and a variety of drugs sufficient to treat all diseases. The benefit will save seniors who currently lack good drug coverage hundreds or even thousands of dollars a year, while giving them access to high-quality medicines. CMS has the authority it needs to review and approve plan formularies, as well as the authority to negotiate with plans on these and other benefit design features. The agency will use this authority to ensure that beneficiaries get the drugs they need at the lowest possible cost.

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Our formulary review process will have to strike a balance between providing plans the flexibility they need to make discount deals with manufacturers and providing beneficiaries with guaranteed access to necessary medications. The USP guidelines are a piece of that process, but by far not the whole process.

6. **When a beneficiary's drug is not covered by a drug plan's formulary that is in compliance with the Guidelines, what recourse will that beneficiary have? How does this appeals process differ from public and private insurance coverage? What standards will beneficiaries have to meet to have the drugs they need covered?**

Answer: We intend to implement the law so that drug plans and Medicare Advantage plans provide coverage for medically necessary drugs that are not excluded from Medicare coverage. As part of achieving this goal, under the law all drug plans are required to have exceptions

processes when people wish to challenge a drug that is not covered on their plan's formulary.

If an enrollee wishes to receive a non-formulary drug – or to receive a non-preferred drug for the lower preferred co-pay – the enrollee or enrollee's physician may request an exception. Under such an exception, a non-formulary drug could be covered, or a non-preferred drug could be covered under the terms applicable for a preferred drug under certain conditions. As part of this process, the prescribing physician would have to determine that the preferred drug (or all the formulary drugs) either would not be as effective for the individual or would have adverse effects for the individual, or both.

We expect that Part D plans will have exceptions criteria that are fast and highly automated much like the market today. For example, we envision an exceptions process similar to Missouri's Medicaid program, which has a computerized system for its prior authorization restrictions. That state's program has the COX-2 inhibitors on prior authorization, since other pain relievers, such as aspirin or ibuprofen, are often just as safe and effective but at much less cost. If a beneficiary tries to fill a Celebrex prescription, the computerized prior authorization system works with the pharmacist to see if they patient meets any of the plan's scientifically established exceptions criteria. These include a prior history of gastrointestinal illness or concurrent use of a blood thinner such as warfarin, among others. If the patient meets the criteria, the coverage is automatically approved. If not, the patient's physician can still challenge the restriction with additional information by a phone-in process.

7. The proposed regulation does not appear to prevent drug plans from limiting the number of prescriptions that could be filled in a month. Is that the case?

Answer: CMS will not allow plans to place arbitrary limits on the number of prescriptions that beneficiaries may fill. The drug benefit is an open-ended entitlement, featuring catastrophic coverage with no upper limit. If a physician prescribes multiple medications for a beneficiary, all are eligible for coverage under the terms of the plan. CMS will work to make this clear in the final rule and in forthcoming sub-regulatory guidance. Plans do have authority to combat waste and fraud by placing reasonable limits on the quantity of medicine dispensed or the frequency of refills, but they cannot, for example, limit the total number of prescriptions filled per month as certain state Medicaid programs do.

8. The proposed rule does not appear to set limits on the type of private information that can be shared with drug plans and HMOs to help them "efficiently" market. Could information about health status or income be shared with plans?

Answer: The beneficiary information given to the plans is intended solely to assist in their outreach to ensure beneficiary education and participation in the drug benefit. The statute provides us broad authority to share information with drug plans and we are concerned of potential adverse impacts on beneficiaries. The information about beneficiaries provided to drug plans must be in accordance with the HIPAA Privacy rule that includes disclosure of protected health information. We encourage input from the public on this very important matter.

9. The proposed rule indicates that drug plans will not be allowed to design a plan that discourages individuals with specific health conditions from enrolling. It appears, however, that a plan could discourage enrollment of sicker people in general, by charging higher cost sharing for all high-cost drugs. Could a plan impose higher cost sharing in this manner and still be approved?

Answer: It is critical to note that by law, the drug benefit must not discriminate against the needs of Medicare beneficiaries, regardless of their health problems. CMS will review all plan benefit designs and will not approve any that appear to be aimed at favorable selection. We clearly have that authority in statute and plan to use it to protect beneficiaries and the taxpayers. We will also be reviewing formularies to ensure that tiering structures do not discriminate against certain beneficiary groups.

10. In order for the prescription drug catastrophic coverage to begin, beneficiaries have to spend a defined amount out of their own pockets. In the proposed regulation, a few other sources count toward that spending, including a pharmaceutical company's assistance program. The regulation does not count spending by the Veterans Administration or the Indian Health Service, which disadvantages the people those programs serve. Can you explain why spending by these agencies does not count toward the out-of-pocket limit?

Answer: The MMA provides that any cost sharing reimbursed or paid for by insurance or otherwise, a group health plan, or another third-party payment arrangement on behalf of a Part D enrollee does not count toward true out of pocket expenditures.

The term "insurance or otherwise" is defined in the NPRM consistent with CMS's policy goal (which we believe to be consistent with Congressional intent) of reducing incentives for current employers, other insurers, and government programs to reduce their current levels of coverage and replace that coverage with Medicare Prescription Drug plan wrap-around benefits. Consistent with our definition, "insurance or otherwise" includes any government-funded program whose principal activity is the direct provision of health care to individuals. Since the principal activity of the Veterans Administration and the Indian Health Service is the direct provision of health care, any cost-sharing the VA or Indian Health Service subsidizes on behalf of Medicare Prescription Drug Benefit enrollees cannot count toward the true out of pocket costs.

The Indian Health Service will benefit from the implementation of the Medicare Prescription Drug Benefits given that prescription drug plans and Medicare Advantage-Prescription Drug plans will reimburse Indian Health Service, Tribal, and urban Indian health program pharmacies for 75 percent of the Medicare Prescription Drug Benefit enrollees' covered drugs under the new benefit spending between the deductible and the initial coverage limit. This reimbursement by plans represents, in many cases, expenses that Indian Health Service and Tribal facilities were previously paying in full on behalf of their beneficiaries.

Questions for the Honorable Mark B McClellan, M.D., Ph.D.
Administrator, Centers for Medicare & Medicaid Services
from the Honorable Orrin Hatch,
Committee on Finance
regarding the September 14, 2004, hearing entitled
"Titles I and II: Features of the Proposed Regulations"

There are more than one million dual eligible beneficiaries as well as additional elderly beneficiaries with mental illnesses who require psychotropic medications. The scope and impact of severe and persistent mental disorders and the cost of treatment is indisputable. The U.S. Department of Health and Human Services in 2003 recognized that four of the top ten leading causes of disability in the United States were indeed psychiatric in origin.

It is clear that the Medicare conferees who drafted the MMA were concerned about ensuring that all Medicare beneficiaries with special needs have access to their medications under Part D. The language in the final conference report is unequivocal. "It is the intent of the conferees that Medicare beneficiaries have access to prescription drugs for the treatment of mental illness and neurological diseases resulting in severe epileptic episodes under the new provisions of Part D. To fulfill this purpose the Administrator of the Center for Medicare Choices [sic] shall take the appropriate steps before the first open enrollment period to ensure that Medicare beneficiaries have clinically appropriate access to pharmaceutical treatments for mental illness, including but not limited to schizophrenia, bipolar disorder, depression, anxiety disorder, dementia, and attention deficit disorder/attention deficit hyperactivity disorder and neurological illnesses resulting in epileptic episodes. (Emphasis added) (Sec. 923 of the Joint Explanatory Statement of the Medicare Conferees, Nov. 21, 2003, p. 321).

The Report of the President's New Freedom Commission on Mental Health cites the critical importance of Medicare and Medicaid Reform to improving the quality and accessibility of mental health service delivery through support of evidence-based treatments. On August 20, 2004, CMS itself published a paper entitled "Psychotropic Medications: Addressing Costs without Restricting Access." The paper stressed that despite the current economic conditions and pressures on states, states have effectively implemented alternative cost management techniques related psychotropic medications without restricting access to specific medications. The paper cites several examples of states as models, including Missouri, Texas and Pennsylvania that have reduced the amount spent on psychotropic medications while not limiting access.

1. **Almost all states have recognized the unique needs of individuals with mental illness and provided exemptions for mental health medications including antipsychotics and antidepressants while employing cost-saving techniques. Physicians are currently able to prescribe medicines to their dual eligible, special-needs populations. When passing the MMA, Congress did not intend to diminish benefits for dual eligible beneficiaries with mental illnesses. After January 1, 2006, how will**

CMS, in its regulations, ensure continuity of care and access to necessary treatment for these special needs patients?

Answer: CMS will not allow plans to place arbitrary limits on the number of prescriptions that beneficiaries may fill. The drug benefit is an open-ended entitlement, featuring catastrophic coverage with no upper limit. If a physician prescribes multiple medications for a beneficiary, all are eligible for coverage under the terms of the plan. The MMA establishes special enrollment periods which will permit dual eligible beneficiaries to change plans if their medications aren't covered. CMS will work to make this clear in the final rule and in forthcoming sub-regulatory guidance. However, plans will have authority to combat waste and fraud by placing reasonable limits on the quantity of medicine dispensed or the frequency of refills, but they cannot, for example, limit the total number of prescriptions filled per month as certain state Medicaid programs do.

All beneficiaries will have access to an appeals process through which they can request coverage for a non-formulary drug, or moving a drug from a high tier to a lower tier. An enrollee, or a prescribing physician on behalf of an enrollee, may file an exceptions request. Although neither are required to submit a physician's certification along with a request for an exception, nothing in the regulation would prohibit an enrollee, or his or her prescribing physician, from submitting a supporting physician's certification with the exceptions request. Plans are permitted to require a prescribing physician to submit a certification supporting the enrollee's exceptions request once a request has been submitted, and CMS expects that plans will routinely ask for them. Therefore, it would benefit enrollees to submit a physician's certification with his or her exceptions request, but they are not required to do so.

CMS will review plan formularies to ensure that Part D plans offer a comprehensive benefit that does not discriminate against beneficiaries with a particular disease or condition, including dual eligibles. In addition, we will review plan administrative control requirements and appeals processes to ensure that vulnerable beneficiaries will have appropriate access to the medications they require.

2. **Although those dual eligible beneficiaries who do not participate in the enrollment process for the prescription drug benefit will be automatically enrolled in the Medicare Part D benefit, how will CMS ensure that those dual eligible beneficiaries who are automatically enrolled in a prescription drug plan maintain the same benefits they received under Medicaid?**

Answer: CMS will not allow plans to place arbitrary limits on the number of prescriptions that beneficiaries may fill. The drug benefit is an open-ended entitlement, featuring catastrophic coverage with no upper limit. If a physician prescribes multiple medications for a beneficiary, all are eligible for coverage under the terms of the plan. The MMA establishes special enrollment periods which will permit dual eligible beneficiaries to change plans if their medications aren't covered. CMS will work to make this clear in the final rule and in forthcoming sub-regulatory guidance. However, plans will have authority to combat waste and fraud by placing reasonable limits on the quantity of medicine dispensed or the frequency of

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Questions for the Honorable Mark B McClellan, M.D., Ph.D.
Administrator, Centers for Medicare & Medicaid Services
from the Honorable Jon Kyl,
Commttee on Finance
regarding the September 14, 2004, hearing entitled
"Titles I and II: Features of the Proposed Regulations"

1. **Dr. McClellan, your office has stated that a large portion of the increase in the Medicare premium stems from the provision in the Medicare Modernization Act that increased the physician payment by 1.5 percent and averted the eminent cut of 4.5 percent. I was adamant to have that increase in physician payment included in the legislation because I had heard from doctors and patients alike about the impact the anticipated reduction would have had on patient access, both in rural, underserved communities and by specialists. This 'fix' in the legislation was temporary; the underlying issue of adequate physician payment and specifically the sustainable growth rate (SGR) formula remains problematic.**

   I, along with my esteemed colleague from Arkansas and member of the Finance Committee, Senator Lincoln, circulated a Dear Colleague letter dated May 25, 2004 addressed to you on the SGR issue. A total of 73 Senators, both Republicans and Democrats, signed the letter, asking for an administrative fix to this problem. As we have yet to receive a written response, can you tell me of your intentions to address the SGR problem administratively in the future? What are your plans to avert the need to correct physician payment increases / decreased by an act of Congress in subsequent years?

Answer: I believe you have since received my response and I am sorry that you did not receive it sooner. I have long shared your concern about making sure that Medicare payments to physicians are adequate and encourage better care, because physician decisions can have such a critical impact on all Medicare costs and on patient health. Now more than ever, we need to work with physicians to find the best ways to improve quality and reduce costs.

I strongly agree with you that we must work together to preserve beneficiaries' access to high quality care. As you point out, as a result of our joint collaboration, enactment of the MMA guarantees the 2005 physician fee schedule update will be no less than 1.5 percent. The MMA improves access to high-quality care by recognizing that Medicare beneficiaries cannot get such care without paying physicians appropriately. We are increasing payments for doctors this year and next, instead of the payment cuts that would have taken effect had this law not been passed. As a result of the MMA, physicians will receive roughly 4 percent more in Medicare revenues in 2004 and 2005.

CMS is also currently working to implement numerous provisions of the MMA that make vital improvements to the Medicare program, such as adding important preventive benefits and taking steps to reward health professionals for avoiding complications and reducing costs. We are also investigating new approaches that may reduce adverse incentives in the current payment system and allow Medicare to pay for better rather than more care. We are implementing innovative

coordinated care and disease management pilots and demonstration programs such as the Chronic Care Improvement Program that may provide insight on new and innovative ways to control expenditure growth in the future. We are currently assessing the impact this significant new law should have on the physician spending targets.

In your letter, you specifically requested that CMS take certain administrative action to address the physician update situation. As I believe you are aware, some of the administrative proposals that you ask about have significant long-term cost implications but will not have an impact in 2006 and the subsequent few years. Therefore, without a change in law, there will still be a reduction in physicians' fee schedule rates for 2006 and subsequent years. Nevertheless, as we consider changes to the physician fee schedule for 2006 and future years, we are committed to looking thoroughly at your suggestions.

Questions for the Honorable Mark B McClellan, M.D., Ph.D.
Administrator, Centers for Medicare & Medicaid Services
from the Honorable Blanche Lincoln,
Committee on Finance
regarding the September 14, 2004, hearing entitled
"Titles I and II: Features of the Proposed Regulations"

1. **Can you please provide me a list of states where those beneficiaries who were automatically enrolled in a Medicare-approved drug discount card are located? (Beneficiaries in some State Pharmacy Assistance Programs and Medicare Advantage Plans were automatically enrolled.)**

Answer: Nine states are auto-enrolling approximately 345,000 of their State Pharmacy Assistance Program (SPAP) beneficiaries into the Medicare drug discount card and transitional assistance (TA) program. These beneficiaries will access the $600 in transitional assistance prior to utilizing the state benefit programs. States that are auto-enrolling include: Connecticut, Maine, Massachusetts, Michigan, New Jersey, New York, North Carolina, Pennsylvania, and Rhode Island.

Each state is auto-enrolling their TA beneficiaries with one sponsor, except Connecticut. Connecticut will be giving their TA beneficiaries a choice of 14 sponsors. If a beneficiary fails to enroll with one of Connecticut's sponsors, the State, at random, will auto-enroll them into a sponsor's plan.

Illinois has passed legislation to auto-enroll its low-income beneficiaries and is working on an administrative rule to administer the auto-enrollment program.

Nevada is also considering auto-enrollment at a later date.

The Medicare Advantage plans automatically enrolled their enrollees into their exclusive drug cards. Most of the MA exclusive cards enrollees are located in Arizona, California, Florida and Pennsylvania.

2. **Can you please provide me a state-by-state list of how many beneficiaries have enrolled in a drug discount card? If you do not have this information, please tell me where I can get it.**

Answer: There are about 4.4 million beneficiaries enrolled in the drug discount card program, which is more than halfway to our goal of 7.3 million beneficiaries for 2004. Currently state-by-state enrollment data is not available. We are working diligently to make these numbers available to you as soon as we can.

3. Can you please provide me a state-by-state list of how many beneficiaries are getting the $600 transitional assistance? If you do not have this information, please tell me where I can get it.

Answer: There are about 1.2 million beneficiaries enrolled in transitional assistance. This is a quarter of low-income beneficiaries we anticipated to enroll in the program for 2004 and 2005. Currently state-by-state enrollment data is not available. We are working diligently to make these numbers available to you as soon as we can.

4. When are you going to define the regions for the PPOs?

Answer: We have sought out and received comments from interested stakeholders on the appropriate number of PDP regions and will be seeking additional public comment again very shortly. We will be announcing a decision on the regions later this year – hopefully by the middle of the fall, though no later than January 1, 2005 as the statute requires).

The law directed CMS to conduct a market study and consider how different regional choices can maximize plan participation. CMS has hired a contractor – RTI International – to conduct that study, which is ongoing. CMS held a public meeting to present options for both sets of regions on Wednesday July 21, 2004 in Chicago, IL and has received scores of comments from potential PDP and MA plan bidders. It is our goal to establish regions that will result in sufficient plan participation to create competitive pressures to drive prices downward, while simultaneously providing beneficiaries with meaningful choice in how they obtain their care.

5. That is the proposed criteria for selecting "fallback plans"? Are there any differences in criteria between fallback and "at-risk" plans? Why?

Answer: As directed by statute, most all of the criteria for selecting fallback plans will mirror those for the at-risk plans – prescription drug plans (PDPs) and Medicare Advantage (MA) plans. All types of plans will set up a benefit design, formulary and utilization management rules, networks of retail pharmacies to provide the benefit, customer service operations to handle beneficiary calls, enrollment teams to sign beneficiaries up. All applicants will have to demonstrate that they can meet standards set by law and by regulation on all these fronts.

The requirements differ between fallback and the others as they relate to competition and insurance risk. Again, these differences are statutory and are reflected in CMS' proposed rule. The PDPs and MA plans will carry insurance risk and compete for beneficiaries on price and quality. Because of this, they will have strong incentives to control premiums and drug prices while providing beneficiaries with the medicines they need. The design for these plans in the MMA relies on this competitive dynamic, and premiums are set entirely on a bid-based system. CMS will evaluate plans' bids to make sure for reasonableness, to make sure they reflect the revenue required. Fallback plans, by definition, will not compete with other plans, as by statute they will only be activated if

at-risk plans fail to enter parts of the country. They will also not carry insurance risk. For these reasons, analysts believe their incentives to control costs are somewhat weaker, and the statute directs CMS to include other performance incentives in its contracts with fallback plans. These incentives are to include cost containment, which will most likely involve performance bonuses related to drug prices and utilization management. CMS is currently working with experts in the field of pharmacy benefit management to devise its performance metrics, and will have further information available in the final rule and in forthcoming guidance as part of the fallback and at-risk bidding processes.

6. **The proposed Medicare formulary classification guidelines place all of the modern antipsychotic medications in the same category – the so-called "atypical" antipsychotics. However, leading experts find this categorization "confusing . . . inappropriate and misleading", and "lack[ing] clear theoretical underpinnings and rigor in application." As one leading researcher put it, "the differences between drugs within this group are just as large as the differences between them and the classical [antipsychotics]." Because the atypical antipsychotic drugs are so different from each other, will CMS place each in its own category? If not, how will CMS ensure that the special population that relies on these medications is not harmed?**

Answer: Medicare will provide seniors with coverage for the medicines they need at the lowest possible price when the new Medicare prescription drug benefit begins in 2006. It makes no sense to create a new prescription drug program that does not cover the drugs seniors take. It is critical to note that by law, the drug benefit must not discriminate against the needs of Medicare beneficiaries, regardless of their health problems. Also, the process to develop clear guidance to prescription drug plans will be public and will examine all aspects of a drug benefit. The Medicare drug benefit will be a *comprehensive* benefit, covering an amount and a variety of drugs sufficient to treat all diseases. The benefit will save seniors who currently lack good drug coverage hundreds or even thousands of dollars a year, while giving them access to high-quality medicines. CMS has the authority it needs to review and approve plan formularies, as well as the authority to negotiate with plans on these and other benefit design features. The agency will use this authority to ensure that beneficiaries get the drugs they need at the lowest possible cost.

The USP model guidelines will be a valuable piece of CMS's formulary review process, but is only one piece of a much bigger pie. In addition to the categories and classes, CMS will review the actual drugs chosen to populate the formulary, the co-pays assigned to the drugs, the exceptions and prior authorization rules, as well as the appeals process. Only when viewing all these pieces together, can one make a judgment about beneficiary access to needed medicines. Two drugs per class is not a hard and fast rule – just a minimum floor. In many cases – AIDS drugs, for example -- I expect significantly more than 2 drugs will be required where they are available, because combinations of anti-viral medications are absolutely critical to keeping the virus at bay.

Our formulary review process will have to strike a balance between providing plans the flexibility they need to make discount deals with manufacturers and providing beneficiaries with guaranteed access to necessary medications. The USP guidelines are a piece of that process, but by far not the whole process.

7. Is the USP recommendation on therapeutic classification significantly different than the classes of drugs currently used by health plans in the private sector to establish formularies? If so, how? Is it different from the VA formulary or the Medicaid formulary, and how?

Answer: The draft guidelines, released by USP in August, have drug categories and classes that are very similar to those used in commercial plans, as well as the VA and Medicaid. This is in keeping with CMS's discussions with the USP expert committee. CMS would like for the model guidelines to reflect the current practice of pharmacy benefit management so that plans will choose to use the guidelines when designing their formularies for Medicare. Recall that plans are not required to use the USP model.

The USP Model Guidelines list 43 major categories and 138 pharmacologic drug classes. This places it well in line with other models. For comparison:

- The Blue Cross/Blue Shield Federal Employee Health Plan (Basic Option) formulary lists 17 major categories and approximately 175 therapeutic drug classes. (Approximately 660 drug products are included on the formulary)

- The Aetna Federal Employee Health Plan formulary lists 17 major categories and approximately 108 therapeutic drug classes. (Approximately 325 brand name drug products and most generically available covered prescription oral products are included on the formulary)

- The Advance PCS 2004 formulary lists 17 major categories and approximately 95 therapeutic classes. (More than 900 drug products are listed on the formulary)

- The Caremark Preferred Drug List has 13 major categories and approximately 158 therapeutic classes. (Approximately 360 brand name drug products are listed and most generically available prescription drug products would be included)

- The Wellpoint formulary lists 26 major categories and approximately 99 therapeutic classes. (More than 650 drug products are listed on the formulary)

As indicated in the previous answer, the categories and classes are only one element of a well constructed formulary Regardless of whether plans use the USP model or develop their own, CMS will review the entirety of the formulary to make sure that beneficiaries have access to the drug they need.

Questions for the Honorable Mark B McClellan, M.D., Ph.D.
Administrator, Centers for Medicare & Medicaid Services
from the Honorable John Rockefeller,
Committee on Finance
regarding the September 14, 2004, hearing entitled
"Titles I and II: Features of the Proposed Regulations"

Staring January 1, 2005, seniors across the country will see an increase of 17.4% in their Medicare part B premiums. This increase amounts to a dollar amount of $11.60 per month and $139.20 for the year. Never in the history of Medicare has the dollar increase in part B premiums been this great.

1. **CMS chose a very unconventional method of making the premium increase announcement. Instead of announcing the 2005 Medicare part B premium increase in October at the same time as the 2005 Social Security cost-of-living-adjustment (COLA), which is typically the case, you chose to announce the premium hike late on a Friday afternoon, before a long weekend when a major hurricane was about to hit Florida. Can you explain why CMS chose to announce the increase in this manner, separate from the COLA announcement? Were you concerned that seniors would be upset to learn that their Medicare part B premium increase would eclipse any increase in the Social Security COLA?**

Answer: CMS is committed to providing information to the beneficiary community in a manner that is as timely as possible. We released these figures at the time we did because that is when the numbers were available and we believed that the importance of these figures merited an earlier than usual release. While some of the changes in the MMA resulted in increases in the Part B premium, for example the changes to physician payments, these changes also addressed a significant problem of potentially reduced access to physician services as a result of significant reductions in payments to physicians that would otherwise have taken effect. Most members of Congress supported increases in payments to doctors because of concerns that beneficiaries might lose needed access to physician services. And while premium costs have increased by more than 17%, costs for some beneficiaries have been reduced as a result of the MMA. For example, beneficiaries who use prescription medications and chose to obtain a Medicare discount drug care saw savings in their drug costs; for some beneficiaries these savings may have surpassed the increase in the Part B premium. Note also Medicare is now covering screening for cardiovascular disease and diabetes for all beneficiaries, as well as a "Welcome to Medicare" physical examination for new beneficiaries. And finally let me point out that the 6 million lowest income beneficiaries do not pay the Part B premium and hence are not affected by the increase for 2005.

2. **West Virginia ranks 3rd in the nation in residents over 65. Fifteen percent of our population is 65 or older. As a result, West Virginia will be hit harder by the premium increase than almost any other state in the country. The premium hike will cost seniors in my state $48.4 million more next year. I am concerned that a**

significant portion of this increase will be going toward subsidies for private plans, which have not and will not come into West Virginia. I understand from press reports that at least 15% of the premium increase is a direct result of subsidies to private plans. Is this true? What is the remaining 85% attributable to?

Answer: The principal contributing factor accounting for about four-fifths of the increase in benefit costs is higher payments in Medicare's traditional plan. In particular, MMA provisions that increased payments to physicians – which had strong bipartisan support – account for more than half of the higher benefit payments related to the traditional plan.

The 2005 premium reflects a Congressionally-mandated increase of 1.5 percent in physician payments for both 2004 and 2005. (Please note that the 2004 premium was set before the enactment of the MMA.) In addition, increases to physician payments under the Consolidated Appropriations Resolution of 2003 are reflected in the premium for 2005.

These changes in physician payments prevented a significant payment reduction that could have threatened access to high-quality physician services for millions of Medicare beneficiaries. Notably, in 2002 the Medicare Rights Center, a beneficiary advocacy organization, forecasted a potential access problem and recommended a review of payment adjustments.

Members of Congress of both parties – including Members who did not vote in favor of final passage of the bill – strongly supported increases in payments to doctors and Medicare Advantage plans, as well as coverage of new preventive benefits.

A much smaller portion (about one-fifth) of the higher Part B benefit costs is due to improvements in Medicare Advantage. As a result of these improvements, many beneficiaries enrolled in Medicare Advantage plans will receive additional benefits including prescription drugs, more preventive care, and even dental and vision care, as well as lower co-payments that enable them to reduce their out of pocket costs.

By law, the amount of a beneficiary's Part B premium increase may not exceed the cost of living increase in his or her Social Security check. In general, the amount of the cost of living increase will be significantly greater than the premium increase of $11.60, but for those Social Security beneficiaries for whom this is not true, the law protects them from a reduction in their Social Security benefits.

And, more than 6 million low-income beneficiaries will see **no** premium increase. These beneficiaries are protected, because they already have their entire premium paid for by Medicaid. In addition, beneficiaries in Medicare Advantage may get help from their plan in paying the Part B premium, and many beneficiaries with retiree coverage get help as well.

3. **Has CMS done any modeling to determine how this premium increase will affect enrollment in traditional Medicare fee-for-service versus Medicare Advantage? Do you anticipate that the 17.4% premium hike will drive even more seniors to Medicare Advantage plans, which again are not widely available in West Virginia?**

Answer: No, we have not done any modeling to determine whether this premium increase may affect enrollment in Medicare Advantage. Under the MMA, regional PPOs are expected to be available across the country, including in West Virginia, beginning in 2006. And it is expected that these MA plans will offer beneficiaries savings compared to fee-for-service Medicare. Therefore, for those beneficiaries who do choose an MA plan, they should see reduced costs compared to obtaining their Medicare benefits through the traditional Medicare fee-for-service program.

Retiree Coverage

As you know, I have written two letters – one to HHS and one to the President – on the loss of retiree coverage under the new Medicare law. Both letters ask that this Administration implement a clear standard that protects employer-sponsored retiree health benefits. Because of your numerous public admissions that this Administration is interested in protecting retiree coverage, I had hoped the proposed regulations would provide meaningful details on your plans to fight the erosion in retiree coverage expected as a result of the new Medicare law. However, the proposed regulations are vague at best. And, they do not provide clear guidance on actuarial equivalence, which is perhaps the single most important component of this law as it relates to retirees.

4. **Why is the so-called "one-prong" test even an option for defining actuarial equivalence when it would allow employers to receive the full subsidy without regard to whether or not they are actually paying an amount for retiree drug coverage that is at least as much as what they are receiving in subsidy payments? Because this "option" would not take into account financing, employers could cost-shift the entire cost of prescription drug coverage onto their retirees while still receiving the subsidy. This is the same problem that exists under current law, so why would CMS consider such an option?**

Answer: In the proposed rule, we discussed several options for defining actuarial equivalence in the context of the retiree drug subsidy. We specifically sought comments and additional data on the best combination of approaches to achieve our goal of providing the maximum improvement in retiree coverage at the least cost.

Under all of the alternatives presented, the amount of support for retiree coverage and thus the generosity of retiree coverage generally increases, because of the combination of contributions from Medicare and from employers.

Allowable retiree costs are defined in the law as the part of the gross covered prescription drugs costs under a qualified retiree prescription drug plan that are actually paid (net of discounts, chargebacks, and average percentage rebates) by the sponsor or by or on behalf of a qualifying covered retiree. In the proposed rule, we asked for comments on the nature and scope of price concession and how to best account for all price concessions and rebates.

5. Is CMS considering any type of maintenance of effort requirement to prevent employers who are offering more comprehensive retiree coverage than the Medicare standard benefit from reducing their retiree benefits to the level of Medicare?

Answer: Employer-sponsored coverage was in decline before the MMA was enacted. This important new law now offers considerable financial incentives to encourage employers to continue providing this coverage. We believe that Medicare Part D, including the retiree drug subsidy and the other options it gives employers for providing enhanced drug coverage, will help to counteract this trend by increasing the financial support available to employers for retiree drug coverage.

We anticipate the options made available by the MMA will not only protect, but also will enhance coverage offered to retirees. The retiree drug subsidy puts new money on the table to encourage employers to continue offering the high quality benefits they currently provide. Retiree plan sponsors must offer coverage at least as generous as the standard Medicare prescription drug benefit to qualify for the tax-free subsidy payments.

6. What is the definition of a plan for purposes of determining actuarial equivalence?

Answer: The term "group health plan" is defined in section 607(1) of ERISA. With respect to which health benefits are included within a sponsor's group health plan for determining actuarial equivalence, we proposed to presume that all health benefits provided by a sponsor are under a single group health plan unless it is clear that one or more health benefits comprise a separate group health plan. We recognize that there is tremendous diversity and complexity among retiree drug plans, and believe our proposed approach preserves sponsor's flexibility.

7. How is CMS planning to verify an employer's attestation that it has met the actuarial equivalence standard? At an August 19 public forum on this issue, Steve Lieberman admitted that CMS has no experience in this area. Have you met with (or are you planning to meet with) unions and employers to discuss employer disclosure requirements? Have you thought about an audit and enforcement mechanism? Will there be an appropriate appeals process for unions and/or beneficiaries?

Answer: The law requires that the audits of sponsors of retiree prescription drug programs that receive a subsidy be similar to the audits of MA organizations and PDP sponsors. We proposed that the sponsor of the plan (or designated plan administrator, insurer, or group health plan) would be required to maintain and provide access to sufficient records for our audits or audits of the Office of Inspector General to assure the accuracy of the attestation of actuarial equivalency with the standard Part D benefit and the accuracy of subsidy payments. We have held a special open door forum to discuss the retiree subsidy and numerous participants provided feedback on the issue of employer attestation. We welcome the valuable input of employers and unions as we develop the final rule.

8. CMS has proposed four "options" for employers with regard to retiree coverage. Does the CMS Office of the Actuary have estimates on how each "option" would affect the employer drop rate? On July 23, the *New York Times* published an article which indicated that one of the "options" that CMS rejected would have caused at least 3.8 million retirees to lose their employer-sponsored prescription drug coverage in 2006. Can you tell me what this rejected "option" was?

Answer: According to the CMS Office of the Actuary (OACT), there is considerable uncertainty associated with how employers will react to the new Medicare drug benefit. The additional information we are seeking from employers and unions and their advisors through the proposed rule should help reduce the uncertainty and facilitate the preparation of specific estimates of the extent to which employers will take each of the available options.

Employers and unions will have several options to participate in their retirees' drug coverage. They can continue offering primary retiree prescription drug coverage and accept the new Medicare retiree drug subsidy. They can supplement the new Medicare drug benefit either by paying basic and / or supplemental premiums, or by providing "wrap-around" coverage that fills in some of the cost sharing. Employers or unions can also contract with drug plans or Medicare Advantage plans to provide enhanced benefits. Lastly, sponsors can qualify as Medicare prescription drug plans and directly offer enhanced benefits to their retiree-beneficiaries.

OACT did not estimate the number of retirees retaining employer coverage where Medicare drug coverage is primary (because the beneficiaries are enrolled in a Medicare Part D plan). OACT's preliminary assessment is that the majority of such beneficiaries probably would not receive drug benefit coverage through their employer. One reason, as noted below, is that some retirees are in plans where employers make no contribution to the costs of drug coverage. Such employers are unlikely to make contributions to "wrap around" Medicare. Instead, these retirees are likely to be substantially better off financially by replacing their current, unsubsidized retiree coverage with the new subsidized Medicare drug coverage. OACT is continuing to investigate the likelihood of each possibility and hopes to be able to make more specific estimates in the future.

The New York Times story was incorrect, and it does not reflect the policies that we present in the proposed rule. The 3.8 million appears to be based on a proposal that was previously rejected because it did not adequately protect benefits for seniors under Medicare. Under all of the options we are considering in the proposed rule, the amount of support and the generosity of support is significantly higher for retiree coverage – not lower, as the story implied.

We are taking great pains to ensure that benefits are protected -- and expanded -- under the Medicare Modernization Act. That is precisely why we are only considering proposals that enhance retiree coverage.

9. Employers that decide to remain the primary insurers for their retirees will receive a 28 percent subsidy equal to $611 per retiree in 2006. However, employers that decide to drop their comprehensive retiree drug benefits and wrap-around Medicare Part D will receive incur savings of approximately $900 per retiree in 2006. Isn't CMS at all concerned about the incentive created by this law for

employers to drop their retiree prescription drug coverage and enroll their retirees in less comprehensive Medicare plans?

Answer: We are taking great pains to ensure that benefits are protected -- and expanded -- under the Medicare Modernization Act. That is precisely why we are only considering proposals that enhance retiree coverage. To stop the strong trend of dropping coverage that has been occurring for more than a decade, we have outlined four approaches in our proposed rule that we intend to use to get the maximum increase in support for retiree coverage.

The CMS Office of the Actuary (OACT) estimates that Medicare payments for the retiree drug subsidy will average $611 per beneficiary in 2006. In addition, employers with corporate tax liability will also benefit from the exclusion of this payment from taxable income. For employers with a marginal tax rate of 35%, the tax exclusion makes the Medicare payment equivalent to a taxable payment of $940.

All of the options permit enhanced coverage at a lower cost than employers are paying today. Many employers offer enhanced Medicare coverage for Part A and Part B benefits today by wrapping around Medicare's standard coverage, and some have expressed interest in doing this for Part D benefits. In addition, some employers do not contribute enough to the cost of retiree coverage to meet the actuarial equivalence test, which will prohibit any employer windfalls. Retirees in these plans may still be able to get more generous coverage than they have today, however, through the other options.

While we sought comment on this set of approaches to enhancing retiree coverage, one thing is clear: under all of the approaches we are considering, the combined contributions by employers and Medicare for drug coverage on behalf of retirees will generally being greater - and frequently significantly greater - than they otherwise would have been. This means stronger retiree coverage – and the main question for the comment period is how do we make it as much stronger as possible.

10. CMS has often pointed to the exclusion of the 28 percent subsidy from taxable income as a reason for employers to remain primary insurers. However, the tax benefit for each employer is different based on each employer's marginal tax rate. Furthermore, there are many employers who do not incur corporate tax liability at all and, therefore, would receive no benefit from the tax exclusion. Does CMS have any concrete numbers on the number of employers with retiree coverage that have corporate tax liability? How many employers with retiree coverage do not have corporate tax liability?

Answer: CMS does not have data on the tax liability of employers offering retiree drug coverage. According to the CMS Office of the Actuary (OACT), there is considerable uncertainty associated with how employers will react to the new Medicare drug benefit. The additional information we are seeking from employers and unions and their advisors through the proposed rule should help reduce the uncertainty and facilitate the preparation of specific estimates of the extent to which employers will take each of the available options. OACT is continuing to investigate the likelihood of each possibility and hopes to be able to make more

specific estimates in the future.

11. For employers that decide to become Part D plans and receive the higher subsidies paid to private plans, how will the TROOP definition affect their reinsurance subsidies?

Answer: By law, only cost-sharing paid by certain sources counts toward the drug benefit's out of pocket limit, which defines the start of the catastrophic coverage. These sources include:

- The enrollee (or another person on behalf of the enrollee)
- CMS (on behalf of a low-income enrollee who qualifies.for low-income subsidies), and
- A State Pharmaceutical Assistance Program (SPAP)

Congress chose to distinguish between payers of out-of-pocket costs in order to encourage current employers, other insurers, and government programs to continue offering prescription drug coverage when the Medicare drug benefit begins.

In the proposed rule, we propose to extend the above list slightly to include charities unaffiliated with insurers or the beneficiary's employer. We do this by proposing to define "person" (first bullet, above) in the legal sense of the word, to includes unrelated corporations, so charities that are not connected to insurers or the beneficiary's employer could have a role in helping beneficiaries with their out-of-pocket costs.

The proposed rule also outlines specific insurance and government programs that will not count toward the out-of-pocket limit. These include cost-sharing obligations subsidized in whole or in part by employers, other insurers, and government programs (for example, the Indian Health Service (IHS), Department of Veterans Affairs (VA), Department of Labor Federal Workers' Compensation Program, Federally Qualified Health Centers (FQHCs); Medicaid; the State Children's Health Insurance Program (SCHIP); black lung benefits; Ryan White CARE Act funds; and State special funds that assist certain individuals with their medical costs).

12. What type of system is CMS putting into place to monitor prescription drug payments from various payers and their impact on the TROOP definition?

Answer: The new Medicare drug plans and Medicare Advantage plans are responsible for coordination of benefits with state pharmacy assistance programs (SPAPs) and other insurers (including Medicaid programs, group health plans, the Federal Employees Health Benefits Plan (FEHBP), military coverage (including TRICARE), and other coverage we may specify at a later date), including the tracking of out-of-pocket costs.

While all the details of how information will be shared have not been worked out, under the proposed rule, CMS has responsibility for —

- Determining whether costs for a Part D enrollee are being reimbursed through insurance or otherwise, a group health plan, or other third-party arrangement; and

- Alerting Part D plans in which beneficiaries are enrolled about reimbursement of prescription drug costs they receive through insurance or otherwise, a group health plan, or other third party arrangement.

Prescription Drug Discount Cards

Earlier this week, I participated in two roundtable discussions with seniors in my state. The top two issues they were concerned about were the 17.4% premium increase and the Medicare-approved drug discount cards. There are 41 different Medicare-approved drug discount cards in West Virginia. For a state our size, it is unconscionable to believe there are so many choices. Seniors are frustrated and they are confused. I understand this is not just the case in West Virginia, but throughout the country.

13. Given senior confusion over which discount card to choose, I imagine that enrollment in the discount card program is low relative to expectations. Can you tell me how many West Virginia seniors are enrolled in the discount card program? What is the enrollment in each of the 49 other states?

Answer: There are about 4.4 million beneficiaries enrolled in the drug discount card program, which is more than halfway to our goal of 7.3 million beneficiaries for 2004. Currently state-by-state enrollment data is not available. We are working diligently to make these numbers available to you as soon as we can.

14. CMS took an "any willing provider" approach to accepting companies for participation in the drug discount card program, and this approach has resulted in senior confusion and frustration. Will CMS be more selective in contracting with PDP and MA plans for Part D than they have been in contracting with discount card companies? What standards will CMS use to accept or reject a plan?

Answer: By providing a number of card programs enables beneficiaries to have choices based on the drugs they need and the pharmacies that are closest to them and for them to get the best savings by providing competition amongst the cards. Even with the multiple cards, we have made the enrollment process straightforward and simple. We plan on doing the same with the Part D drug benefit when it become available in 2006.

In order for plans to participate in offering the Part D drug benefit, they will have to meet all of the qualifying criteria established under the regulation. By accepting more than one plan, or multiple plans, for any given region, we will be promoting competition among those plans within the region they serve. This competition will drive prices down and will help both beneficiaries and the Federal government.

It is extremely unlikely that beneficiaries will have to choose from as many options in any one location as they have in the case of drug cards. Still, we intend to provide information on beneficiary drug benefit options in many different forms that will allow beneficiaries to choose the best option for them.

15. Seniors in my state have indicated that one of the main problems with the discount card program is the lack of information. They have trouble getting through to 1-800-MEDICARE and accessing the Medicare website. How are you planning to improve the flow of information to beneficiaries in preparation for full implementation of the law in 2006?

Answer: We have committed significant resources to our outreach efforts these past nine months. This includes mass mailings, broadcast advertising, town hall and Congressional events presentations. Also, we augmented the number of customer service representatives at our call centers from 400 to 3,000 in anticipation for the volume of calls from beneficiaries so that wait time is no more than a few minutes. We have made significant improvements to our website based on beneficiary feedback to make it more user-friendly and information. For example, we have improved the "Price Compare" tool -- available by calling 1-800-MEDICARE or on www.medicare.gov by:

- Revised the zip code radius
- Identifying the top five cards for a low-income beneficiary, based on the total cost of their drugs before and after their $600 credit is used.
- Adding a feature to allow beneficiaries with limited incomes to enroll in the $600 credit by providing their eligibility information over the phone or online instead of completing and mailing a paper enrollment form. (Enrollment in the drug discount card has always been possible over the phone and online.) This may be particularly valuable for those who assist beneficiaries, including beneficiary advocates, who can now provide complete enrollment in the drug card and the transitional assistance at one time.
- Adding a new pharmacy search feature that allows users to select the drug card program or programs available at their local pharmacies. They can also get detailed cost information about that local pharmacy. This feature is particularly important to seniors who prefer to use their local pharmacy for their prescription needs.
- Adding new features to make it easier to get additional information about the drug manufacturer wraparound programs that provide large additional discounts on certain name-brand drugs. The website will display a link to get more information about the programs.
- Making significant improvements to the drug entry tool making it quicker for users to enter their drug information, including entering all drug information at one time;
- Improving the display of drug pricing information making it easier for users to compare the price differences between brand and generic drugs;

These new improvements are part of our aggressive effort to make sure seniors and others on Medicare have all the tools we can come up with to help them save money on their prescriptions.

In addition, we have also partnered with community-based organizations, states, and other federal agencies such as AoA to outreach to beneficiaries about the drug card and we have awarded funding to State Health Insurance Assistance Programs (SHIPs), community-based organizations and ABC Coalition. We anticipate continuing this high level of outreach activity through the Part D benefit implementation and enrollment period as well.

Section 641 Demonstration Project

On Saturday, September 11, the *New York Times* reported that less than 4,000 Medicare participants are enrolled in and fewer than 7,000 have submitted applications for the Medicare Section 641 demonstration project. As the author, along with Senator Snowe, of the legislation upon which this demonstration is based, I was extremely dismayed to learn enrollment is this low, particularly since the enrollment deadline of September 30 is fast-approaching. By HHS' own estimation, between 500,000 and 600,000 Medicare participants could be eligible for this demonstration project, but less than 2 percent of those eligible have applied.

16. What is the exact number of beneficiaries enrolled in the demonstration? How many beneficiaries have submitted applications? Why does CMS believe enrollment is so low?

Answer: We have enrolled approximately 4,000 people so far as part of the early enrollment process that ended on August 16th. We have approximately 9,200 applications submitted as of September 24th (this includes the 4,000 already enrolled). We do not believe enrollment is low because we did not intend to enroll all beneficiaries by the August deadline. Our primary goal right now is to make sure that all beneficiaries who can benefit from this demonstration projects are aware of it and make the choice to apply.

17. West Virginia has the 4th highest cancer death rate in the nation. Yet, the constituents in my state remain largely unaware of this demonstration project, and I fear this is probably the case throughout the country. Have HHS and CMS done any direct outreach to the states regarding this demonstration project?

Answer: Our goal is to make sure that all beneficiaries who can benefit from this demonstration projects are aware of it and make the choice to apply. CMS and HHS has worked with the Regional Offices, State Health Insurance Assistance Programs, and other state organizations to provide direct outreach to the states regarding this Medicare demonstration project.

18. Earlier this year, HHS sent a flyer to all Medicare beneficiaries with information about provisions in the Medicare law, even though the law will not go into effect until 2006. According to the Government Printing Office, this flyer cost taxpayers $10 million – $3.2 million in printing costs and $6.8 million in mailing costs. HHS

spent an additional $9.5 million on television ads announcing the new law, again despite the fact that the law will not go into effect until 2006.

Given the imminent nature of this demonstration project and the short timeframe between the launch date of June 24 and the enrollment deadline of September 30, it would have been appropriate for HHS to initiate a comprehensive outreach and enrollment campaign immediately following program launch. How do your outreach efforts on the Section 641 demonstration project compare to your earlier efforts? Have you done any direct mailings to Medicare beneficiaries on the demonstration? What is the total dollar amount you have spent on outreach for this demonstration project?

Answer: Our initial efforts for this demonstration started last Spring and were primarily focused on beneficiary advocacy groups, pharmaceutical companies and physicians who care for patients with the conditions listed in the demonstration project. All of these groups have put articles in their newsletters, sent out mailings and/or put links on their websites to get the message out about this project.

Since then, we have conducted various outreach activities at the local level working with CMS regional offices and SHIPs. We have also worked with key advocacy organizations, disease groups, health plans and drug store groups to reach out to beneficiaries who use the covered drugs. Also, some MA plans that offer limited drug benefits have sent targeted letters to eligible beneficiaries in their plans. We are encouraging PDP plans to do the same sort of outreach.

Information about the demonstration also comes up on CMS Price Compare website when a beneficiary indicates they are taking one of the demonstration's covered drugs.

In addition, we had an article in the September 12th issue of Parade Magazine (Sunday newspaper supplement). Also this past week, special pharmacy newsletters started printing out in selected pharmacies (approximately one-third of pharmacies) across the country when beneficiaries fill a prescription for one of the demonstration's covered drugs. The newsletter includes information about the demonstration and how to apply.

We purposely did not do direct mailings to Medicare beneficiaries for this demonstration project because of the relatively small number of beneficiaries affected. We were concerned with adding confusion and information overload with what is already out there to beneficiaries about the drug discount card, Part D, etc.

It is difficult to quantify the amount specifically used for outreach because it primarily involves staff time presenting at meetings and corresponding with interested groups. We are spending approximately $100,000 through Trailblazer for the special pharmacy newsletters print out when beneficiaries fill a prescription for one of the demonstration's covered drug.

19. Given the low enrollment, is CMS planning to do additional outreach over the next two weeks? Will CMS extend the enrollment deadline beyond September 30 if the enrollment limit of 50,000 participants is not met by that date?

Answer: Our primary objective right now is to make sure that beneficiaries who are eligible apply to the demonstration project. We are planning additional outreach to ensure beneficiaries who benefit from this program enroll. When the September 30th enrollment deadline passes and the 50,000 beneficiaries limit has not been reached then we will have a "rolling" enrollment period until we reach the limit.

Authorized Generics

Dr. McClellan, the Medicare law includes several provisions aimed at improving access to generic drugs. Specifically, the Medicare law includes provisions that eliminate the 30-month stay for brand name manufacturers and strengthen the 180-day period of market exclusivity for generic manufacturers. While I believe these two provisions take a step in the right direction, I am concerned that brand name manufacturers have found another loophole in the law to exploit. It is my understanding that brand name companies are using the so-called "authorized generics" designation in order to sell brand name drugs as generics and have an effective monopoly on the prescription drug market.

20. Both CMS and the FDA appear to be treating "authorized generics" in a manner inconsistent with the intent of Hatch-Waxman. I am hoping that you can use both your FDA and CMS hats to shed some light on this issue. According to the FDA's decision regarding authorized generics, dated July 2, 2004, the FDA defines authorized generics as brand name drugs sold at generic prices. Can you offer any insight into why the FDA would make such a decision, given the fact that this interpretation undermines the 180 days of market exclusivity for true generics and allows brand names to disguise themselves as generics while not having to play by the rules of the generic industry?

Answer: As I am no longer in charge of the FDA, and was not there during July of this year, I would have to refer you to FDA for an answer to this specific question.

21. It is my understanding that CMS treats "authorized generics" as generic drugs as long as the authorized generic label has a different NDC code from the brand label, even though it is the same product. Can you explain why CMS would provide such special treatment to "authorized generics?"

Answer: We understand authorized generics to be those drug products manufactured pursuant to a brand manufacturer's new drug application, which are relabeled and marketed as a "generic drugs" under a separate national drug code (NDC). The law defines innovator multiple source drugs as multiple source drugs marketed under an original new drug application approved by the FDA. Generally, if a drug is approved under an NDA, it is not considered a non-innovator (generic) drug. For authorized generics, the innovator multiple source (brand name) drug would continue to be considered a brand name drug even if it were re-packaged with a different NDC code as an "authorized generic" drug. The National Rebate Agreement also provides that a covered outpatient drug marketed by a cross-licensed producer or distributor under the approved NDA should also be included an innovator multiple source drug.

22. Isn't it true that CMS' treatment of "authorized generics" undermines rebates to the federal government under Medicaid Best Price because brand name manufacturers don't have to report the prices of "authorized generics" as part of the calculation?

Answer: We understand your concerns. We are concerned that this is a pathway for reducing rebates for the Medicaid program and we anticipate addressing this issue in early 2005.

Questions for the Honorable Mark B McClellan, M.D., Ph.D.
Administrator, Centers for Medicare & Medicaid Services
from the Honorable Gordon Smith,
Committee on Finance
regarding the September 14, 2004, hearing entitled
"Titles I and II: Features of the Proposed Regulations"

1. **Almost all states have recognized the unique needs of individuals with mental illness and provided exemptions for mental health medications including antipsychotic and antidepressants when employing cost-saving techniques. When passing the MMA, Congress worked to ensure that dual eligible beneficiaries, especially those with mental illnesses would continue to have access to the same level of coverage received under Medicaid. Please explain how CMS will ensure continuity of care and access to necessary treatment for these special needs patients.**

Answer: CMS will not allow plans to place arbitrary limits on the number of prescriptions that beneficiaries may fill. The drug benefit is an open-ended entitlement, featuring catastrophic coverage with no upper limit. If a physician prescribes multiple medications for a beneficiary, all are eligible for coverage under the terms of the plan. CMS will work to make this clear in the final rule and in forthcoming sub-regulatory guidance. However, plans will have authority to combat waste and fraud by placing reasonable limits on the quantity of medicine dispensed or on the frequency of refills, but they cannot, for example, limit the total number of prescriptions filled per month as certain state Medicaid programs do.

All beneficiaries will have access to an appeals process through which they can request coverage for a non-formulary drug, or moving a drug from a high tier to a lower tier. An enrollee, or a prescribing physician on behalf of an enrollee, may file an exceptions request. Although neither are required to submit a physician's certification along with a request for an exception, nothing in the regulation would prohibit an enrollee, or his or her prescribing physician, from submitting a supporting physician's certification with the exceptions request. Plans are permitted to require a prescribing physician to submit a certification supporting the enrollee's exceptions request once a request has been submitted, and CMS expects that plans will routinely ask for them. Therefore, it would benefit enrollees to submit a physician's certification with his or her exceptions request, but they are not required to do so.

CMS will review plan formularies to ensure that Part D plans offer a comprehensive benefit that does not discriminate against beneficiaries with a particular disease or condition. In addition, we will review plan administrative control requirements and appeals processes to ensure that vulnerable beneficiaries will have appropriate access to the medications they require.

2. **Dual eligible beneficiaries who do not participate in the enrollment process for the prescription drug benefit will be automatically enrolled in the Medicare Part D benefit. However, please explain how CMS will ensure that dual eligible beneficiaries who are automatically enrolled in a prescription drug plan continue to receive a benefit that is of the same value they would have received under Medicaid.**

Answer: CMS will not allow plans to place arbitrary limits on the number of prescriptions that beneficiaries may fill. The drug benefit is an open-ended entitlement, featuring catastrophic coverage with no upper limit. If a physician prescribes multiple medications for a beneficiary, all are eligible for coverage under the terms of the plan. CMS will work to make this clear in the final rule and in forthcoming sub-regulatory guidance. However, plans will have authority to combat waste and fraud by placing reasonable limits on the quantity of medicine dispensed or on the frequency of refills, but they cannot, for example, limit the total number of prescriptions filled per month as certain state Medicaid programs do.

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Questions for the Honorable Mark B McClellan, M.D., Ph.D.
Administrator, Centers for Medicare & Medicaid Services
from the Honorable Olympia Snowe,
Committee on Finance
regarding the September 14, 2004, hearing entitled
"Titles I and II: Features of the Proposed Regulations"

Oral Drug Benefit (Part 641 Demonstration Project)

The Part 641 Demonstration Project was designed to cover up to 50,000 individuals with funding of $500 million to provide coverage of drugs for cancer and other serious diseases. To date, approximately 6700 individuals have filed applications to participate, and 3721 are enrolled. While enrollment is allowed after the September 30 deadline, I am concerned that too many Americans may be unaware of this benefit, and may lack access to essential drugs which Senator Rockefeller and I, as well as many others, fought so hard to obtain.

It appears that those individuals who are in contact with the various disease advocacy groups have been informed, but I don't recall any mention of the program in the media, outside of the initial press announcements.

The efforts to make seniors aware of the drug card and Part D benefits have been laudable. I note television and radio advertising that urges seniors to be aware of the benefits they may receive through the discount cards, and soon, through the Part D program. I am disappointed that many Medicare beneficiaries may not be aware of the existence of a program that provides such critically important assistance today.

1. **What, if any, plans does CMS have to promote the Part 641 benefit, so that many other Americans, especially those perhaps not as plugged into the advocacy groups, can be made aware of the assistance they can receive?**

Answer: Our goal is to make sure that all beneficiaries who can benefit from this demonstration projects are aware of it and make the choice to apply. Our initial efforts for this demonstration started last Spring and were primarily focused on beneficiary advocacy groups, pharmaceutical companies and physicians who care for patients with the conditions listed in the demonstration project. All of these groups have put articles in their newsletters, sent out mailings and/or put links on their websites to get the message out about this project.

Since then, we have conducted various outreach activities at the local level working with CMS regional offices and SHIPs. We have also worked with key advocacy organizations, disease groups, health plans and drug store groups to reach out to beneficiaries who use the covered drugs. Also, some MA plans that offer limited drug benefits have sent targeted letters to eligible beneficiaries in their plans. We are encouraging PDP plans to do the same sort of outreach.

Information about the demonstration also comes up on CMS Price Compare website when a beneficiary indicates they are taking one of the demonstration's covered drugs.

In addition, we had an article in the September 12th issue of Parade Magazine (Sunday newspaper supplement). Also this past week, special pharmacy newsletters started printing out in selected pharmacies (approximately one-third of pharmacies) across the country when beneficiaries fill a prescription for one of the demonstration's covered drugs. The newsletter includes information about the demonstration and how to apply.

Medicare Advantage Subsidy

Part B beneficiaries have just been faced with a 17.5 percent increase in the premiums they pay. While most of this increase related to a change in provider payments and some enhancements to Medicare, such as the new enrollee physical, a significant portion subsidized the Medicare Advantage plans. You cited that approximately 20% of the Part B premium increase could be attributed to incentive payments made to Medicare Advantage plans. The Medicare Modernization Act establishes that the MA Regional Plan Stabilization Fund makes expenditures from both the Part A and Part B Trust Fund. I have not seen any report of the level of subsidy from the Part A Fund.

2. **What is the level of funding which will be drawn from the Part A fund to further subsidize Medicare Advantage in 2005?**

Answer: Payments to Medicare Advantage cover both Part A and B services, thus funds are drawn down from both the Hospital Insurance (HI) and Supplementary Medical Insurance (SMI) trust funds. At the most fundamental level, the percentage of funding drawn down from Part A to subsidize Medicare Advantage in 2005 will be proportional to the number of enrollees in Medicare Advantage and to the proportion of Part A services utilized. Specifically, since Medicare Advantage plans are paid on a capitated payment rate basis, the specific payment amount (i.e., how much from Part A and how much from Part B) is determined through a complex formula based on the distribution of fee-for-service expenditures for Parts A and B.

3. **How will Medicare Advantage incentive funding expenditures be allocated going forward? In other words, is the $10 billion allocated to Medicare Advantage being allocated equally over the seven years of 2007 to 2013, or is the annual expenditure determined in another way?**

Answer: The stabilization fund, used to make additional payments to regional plans to enter or remain in a region, will be initially funded at $10 billion. In addition to this lump sum, the stabilization fund will be supplemented by regional MA plan rebate dollars (half of the 25% rebate CMS receives when MA plans bid below the benchmark). The initial $10 billion has limited availability in that it is only available for regional plans between 2007-2013. After which, the stabilization fund will only be funded by rebate dollars.

It's important to note that a limit has not been placed on the amount that may be spent in the initial years of the fund. However, the regulation makes clear that sufficient funds will need to be available at the beginning of each year so that payments may be made for the entire year and

that expenditures may not exceed the amount available in the fund. CMS will take steps to ensure that sufficient funds are available by computing lower payment amounts or limitations on enrollment in MA regional plans receiving the payments, for example.

Asset Test

You have said that you want to simplify the asset test and that it will not apply to things like wedding rings and other family heirlooms. That has undoubtedly provided some level of comfort to many seniors. However, the exact words in your proposed regulation say anything that can be "readily" sold for cash within 20 days will be counted, which could include all sorts of things.

4. Wouldn't the best way to simplify the asset test, aside from eliminating it, be to provide a finite list of liquid assets, like bank accounts, that will be counted, and then to exclude anything not on that list?

Answer: Given that the MMA requires an asset test, it isn't within the Secretary's discretion to eliminate it. The statute specifically requires a resource test for the low-income subsidy. However, we are proposing in our regulation to simplify this test by excluding a number of assets, including a vehicle, the family home and adjacent property and household contents. Specifically, resources that will be counted generally include liquid resources that can be readily converted to cash within 20 days (e.g., checking and savings accounts) and real estate that is not the applicant's primary residence. The resources of the applicant and the spouse, if any, will be counted to determine if the applicant meets the resource threshold to be subsidy eligible.

5. The asset test might send the wrong message to individuals. We tell people to save for retirement, but then if they do we give them less of a drug benefit. As an economist as well as a physician, I'm sure you share my concern that we encourage savings for retirement. Have you examined research on asset tests and their impact on savings? Is there adequate information on behavior in this area to guide us in formulating policy?

Answer: We have not looked at the research on the effect of asset tests on people's willingness to save for retirement. Because the statute requires an asset test, one that is more generous than in current law, we did not consider its effects when drafting the proposed regulation.

Mental Health and Disenrollment

The proposal would permit a plan from disenrolling an individual if the individual's behavior is disruptive, unruly, abusive, uncooperative or threatening, 423.44(d)(2)(i). The proposal states that behavior would be disruptive if it jeopardizes the health or safety of the beneficiary or the health and safety of others, 423.44(d)(2)(i)(A). However, the proposed regulations do not address cases where a beneficiary's behavior may be unruly due to issues of mental capacity.

6. What about cases where an individual's behavior was "disruptive" due to mental capacity issues? What is meant by "disruptive" behavior?

Answer: Current regulations generally prevent an individual from being disenrolled from a MA plan for behavior related to "diminished mental capacity". However, the unintended impact of these regulations has been to prohibit plans from disenrolling any individual whose violent and threatening behavior jeopardized the health and safety of enrollees, staff, and the public. The proposed regulations would allow CMS to permit disenrollment in those circumstances, while still requiring that MA organizations make serious efforts to resolve problems related to an enrollee's disruptive behavior and require CMS's review and approval of any disenrollments for disruptive behavior.

Disruptive behavior includes behavior that jeopardizes the health or safety of the individual or others or impairs the plan or pharmacy's ability to furnish services to either the individual or others; or someone with decision-making capacity that refuses to comply with the material terms of the enrollment agreement.

Physician Prescribing

The complexities of the drug card program may have taught many of us some lessons that can be applied to the 2006 implementation of the Part D benefit. While beneficiaries struggled to compare cards, we may see physicians struggling to perform appropriate prescribing in 2006. It will be important to know what drugs are covered under the patient's drug plan formulary, and to work with the patient to provide both an effective drug, and one which will be affordable. Thus electronic prescribing which places this information on-line seems essential. However, presently electronic prescribing is the exception, and I am concerned that many patients will find that their physician has prescribed a drug which isn't covered under their plan formulary.

7. What steps are you taking to ensure that we minimize this problem, and what is your projection for the availability of appropriate electronic prescribing systems for our beneficiaries' physicians?

Answer: The MMA directs HHS to work with industry experts to establish national standards for electronic prescriptions. That way, doctors, hospitals and pharmacies across the country can be sure that their computer systems are compatible and will work together seamlessly. Beyond the basic drug name and dosage, the electronic prescribing standard will enable doctors and pharmacies to share a wealth of information, including: (1) identifying what other medications the patient is currently taking so that the doctor and the pharmacist can be on the alert for adverse drug interactions; and (2) determining whether the prescribed drug is on the formulary of the patient's drug plan, or if the plan has tiered co-pays, whether the drug is preferred or non-preferred. That way, the doctor will know right there in the examining room whether a therapeutically appropriate switch to a different drug might save the patient some money. Providing this information directly to doctors is expected to cut down on the need for follow-up phone calls between pharmacists and doctors once the patient has reached the pharmacy counter.

The MMA created a special role for the National Committee on Vital and Health Statistics (NCVHS). NCVHS has begun the process of consulting with representatives of physician and pharmacist organizations, experts on electronic prescribing, and standard-setting organizations, among others, and is tasked with recommending electronic prescribing standards to the Secretary of HHS. Under the timeline established in the MMA, electronic prescribing based upon national standards is to be mandatory for participating drug plans by 2009, although CMS expects to mandate a starter set of well-established standards by January 2006.

NCVHS has accelerated its schedule and submitted initial recommendations to the Secretary in September 2004. CMS intends to follow up on those recommended standards quickly and issue a notice of proposed rulemaking for those standards that are already in widespread use and do not require to be pilot tested.

In order to accelerate the next phase of standards adoption, CMS also plans to review programs already in operation to identify successful practices and standards that can be tested in pilot programs, characteristics that lead to successful electronic prescribing programs. These will be tested in the pilot programs required by the MMA, which CMS will conduct in 2006.
The MMA also authorizes the federal government to give grants to doctors to help them buy computers, software, and training to get ready for electronic prescribing. The grants will cover up to half of the doctor's cost of converting to electronic prescribing, and they may be targeted to rural physicians and those who have a large share of Medicare patients.

Employer Plan Subsidy

Many of us are extremely concerned about the erosion of coverage. While health care expenditure growth slowed slightly last year, it appears likely this was a result of a poor economy and declining contributions to coverage by employers, particularly small business. Efforts to maintain employer coverage are of great concern.

I understand that the plan to test "actuarial equivalence" for purposes of determining whether an employer plan qualifies for subsidy will not be based on the individuals, but on an entire group. These analyses must necessarily be complex.

8. Will CMS publish the methodology for the actuarial test?

Answer: We share your concern about the erosion of employer-based coverage, and we are working to encourage employers to continue offering drug coverage to their retirees. Our actuaries are consulting extensively with the American Academy of Actuaries, as well as benefit administrators from many employers to come up with an actuarial equivalence test that will be workable. We expect to publish final policy on the nature of the test in our final rule and to provide extensive technical guidance to aid plan actuaries in making their attestations.

9. How can we promote transparency in the subsidy process, so that retirees may have confidence that employers are not receiving windfalls?

Answer: We are committed to designing an actuarial equivalence test that encourages employers to continue offering prescription drug coverage to retirees while precluding windfalls, and we are confident that we have options in the proposed rule that will accomplish that. As for transparency in the subsidy process, what we have proposed is requiring that employers' actuarial equivalence determine be conducted and signed by a qualified actuary, one who is a member of the American Academy of Actuaries. This organizational affiliation will ensure that the actuary has sufficient qualifications to make these determinations, and that the member adheres to a code of conduct for actuarial work. In addition, CMS will have the ability to audit both the attestation and the eventual drug claims data that the subsidy payments will be based on in order to combat fraud and abuse.

10. Has CMS committed to use of a "two pronged", rather than a "single pronged" test?

Answer: We share your concern about preventing windfalls, and the two pronged test is most consistent with that goal. In the proposed rule, we outlined multiple approaches to structuring the two pronged test, and we look forward to getting comments and feedback from plan and employer groups on which test is most workable and appropriate. We will publish a final decision on our actuarial equivalence policy in our final rule.

Testimony of Mark Merritt

President & Chief Executive Officer

Pharmaceutical Care Management Association

Before the

UNITED STATES SENATE
COMMITTEE ON FINANCE

Implementing the Medicare Prescription Drug Benefit and Medicare Advantage Program: Perspectives on the Proposed Rules

September 14, 2004

Introduction

Good morning Chairman Grassley, Ranking Member Senator Baucus, and Members of the Committee. I am Mark Merritt, President and Chief Executive Officer of the Pharmaceutical Care Management Association (PCMA). I am pleased to be here today to discuss the proposed rules for implementation of the new Medicare prescription drug benefit.

As background, PCMA is the national association representing America's pharmacy benefit managers (PBMs). PCMA represents both independent, stand-alone PBMs and health plans' PBM subsidiaries. With as many 60 PBMs operating nationally and regionally under a variety of business models,[1] PBMs offer public and private purchasers a wide variety of choices to meet the needs of their plan members. Together, PCMA member companies administer prescription drug plans that provide access to safe, effective, and affordable prescription drugs for more than 200 million Americans in private and public health care programs, including an estimated 65 percent of Medicare beneficiaries who have prescription drug benefits through employer and union-sponsored retiree health plans.[2] Because of the variations among PBMs, it is important that the rules governing Medicare prescription drug plans remain as flexible as possible to encourage the maximum amount of participation of PBMs and offer the widest range of choices to beneficiaries.

Protecting PBMs' Proven Tools & Techniques

PCMA believes strongly that preserving and protecting the cost containment and quality improvement features of the Medicare Modernization Act should be job one as the Administration receives input into the new rules governing the new drug benefit. Ensuring that PBMs are able to participate effectively in Medicare will mean more cost savings for the program and, therefore, more resources available to assure beneficiaries – including those individuals managing complex conditions – access to the prescription drugs they need.

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[1] Federal Trade Commission & Department of Justice, "Improving Health Care: A Dose of Competition," Chapter 7, page 14, July 2004.

[2] Centers for Medicare & Medicaid Services, "Study of Pharmaceutical Benefit Management,"Conducted by PricewaterhouseCoopers, June 2001.

In the commercial marketplace, PBMs have relied upon a broad range of tools and techniques to expand access, promote quality, improve outcomes, and drive down the cost of prescription drugs. PBMs typically offer purchasers a set of core services from which they can choose that include claims administration; clinically-based services; pharmacy network management; negotiation and administration of product discounts; and mail-service pharmacy. In addition, tools such as drug utilization review, clinical prior authorization, consumer and physician education, disease management, and consumer compliance programs help improve the cost-effectiveness of drug benefits.

PBM Cost Savings

According to a new analysis conducted by PricewaterhouseCoopers, PBMs drive down the cost of prescription drugs for their clients on average by 25 percent – or the cost clients would otherwise incur if they chose not to contract with a PBM. Depending upon the level of pharmacy benefit management sought by an employer, health plan, Taft-Hartley union plan, or state and federal government, the savings can range from 15 percent to as much as 40 percent.[3]

Medicare beneficiaries enrolled in private plans are seeing real savings from PBMs. In 2005 alone, PricewaterhouseCoopers estimates that PBMs will save $937 for each Medicare beneficiary with prescription drug coverage provided through private plans, including Medicare Advantage health plans and employer-sponsored retiree coverage. Other data from the Government Accounting Office and Congressional Budget Office have yielded similar findings.[4]

Clearly, when empowered to do so, PBMs are effective at driving down the cost of prescription drugs and improving quality for beneficiaries. PBMs offer private and public purchasers distinct clinical and cost-containment features. Together, these services help purchasers make decisions about the prescription drug plans they offer to their enrollees. As the Administration

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[3] Commissioned by PCMA and conducted by PricewaterhouseCoopers, "The Value of Pharmacy Benefit Management and the National Cost Impact of Proposed PBM Legislation," July 2004. Available at www.pcmanet.org

[4] Government Accounting Office,"Federal Employees Health Benefits: Effects of Using Pharmacy Benefit Managers on Health Plans, Enrollees, & Pharmacies," January 2003. Congressional Budget Office, "Issues in Designing a Prescription Drug Benefit for Medicare." October 2002.

works collaboratively with stakeholders to structure a workable benefit, it is important to preserve PBMs' proven tools and techniques that provide value to beneficiaries and the Medicare program itself.

Formularies

Formularies are one of the most important tools available for effectively managing prescription drug benefits and assuring that beneficiaries have access to safe, effective, and appropriate drugs while also controlling costs.

PCMA, as with the other stakeholders, has been monitoring the process of the US Pharmacopeia (USP) in developing the model formulary categories and classes. While we believe that the model formulary structure proposed by the USP is somewhat overly detailed, it can serve as a starting point for formulary development. PCMA believes it is not necessary, however, to expand further the number of categories and classes recommended. For example, formularies in the commercial marketplace with 80 to 90 categories of drugs can provide coverage for 500 or more different drugs.

PCMA believes the Medicare Modernization Act strikes the right balance between assuring appropriate beneficiary access to medicines, while allowing plan sponsors enough flexibility to administer the program and manage its costs. PCMA believes strongly that the best way to assure beneficiary access to medicines is to manage the costs of the benefit, both for the government and for the beneficiaries, many of whom will still face considerable out-of-pocket costs for premiums and cost-sharing. If premiums cannot be kept affordable, many seniors will not participate in the program or will drop out as premium costs rise. If out-of-pocket costs are too high, beneficiaries may be forced to go without needed medications.

Pharmacy & Therapeutics Committees

In developing clinically-sound formularies, PBMs rely upon panels of experts, called Pharmacy and Therapeutics (P&T) committees, to make formulary recommendations and develop lists of preferred drugs. P&T committees are largely independent providers and include a variety of specialist physicians, pharmacists, and others with specific clinical knowledge of drugs and pharmacotherapy. These committees serve in an evaluative, educational, and advisory capacity in matters concerning formulary development and management. Primarily, this capacity is served in evaluating drugs for safety and efficacy. Development and maintenance of formularies is an ongoing activity, as they must be continually updated to keep pace with new therapies, recent evidence from clinical research, changes in medical practice, and FDA guidance.

PCMA has concerns regarding the implication in the proposed rule that CMS is considering investing P&T committees with broad authority – beyond their areas of expertise – over administration of the *entire* drug benefit offered by a prescription drug plan. P&T committee expertise lies in the evaluation of clinical safety and efficacy and typically does not have the financial and administrative management expertise necessary to develop and manage drug benefits. Considering most P&T committees are independent from the PBM or drug plan, it would not be appropriate for them to be given authority for making decisions that affect a plan sponsor when they have no accountability for those decisions. For these reasons, it is vital that P&T committees fulfill the role envisioned in the Medicare Modernization Act to provide clinical recommendations in developing the formulary. Policymakers should proceed with great caution before investing these clinical experts with the authority to manage and administer an entire drug benefit plan.

E-prescribing

PCMA commends the Administration and Members of Congress from both sides of the aisle for the assertive stance they have adopted on the development of electronic prescribing, or e-prescribing. Republicans and Democrats alike have recognized that e-prescribing holds the promise of reducing drug-related medical errors and improving safety through the application of enhanced technology.

As CMS works to implement e-prescribing standards into the Medicare program – initial standards are due just one year from now, with a pilot program to commence in 2006 – it is critical to recognize that PBMs are at the forefront of implementing e-prescribing programs in the commercial marketplace. Standard PBM e-prescribing features, including information related to patient medication history, formulary information, and claims payment, are the very attributes that Congress intended to inject into Medicare e-prescribing programs with the Medicare Modernization Act. PCMA commends the expedient and diligent work of the National Committee on Vital Health Statistics (NCVHS) and believe the Committee's initial recommendations to the Secretary appropriately look to existing e-prescribing frameworks to ensure seamless standard implementation.

PCMA will continue to work with the Administration and Congress on a bipartisan basis to expedite the development of e-prescribing standards and the eventual implementation of a uniform system. In particular, PCMA will be working for e-prescribing standards that ensure physicians have the right information -- including both clinical data and formulary information – and can work with patients to choose the drug that best meets a patient's overall needs. In addition, PCMA will be working to maintain the mail-service pharmacy option, a proven avenue to lower prescription drug costs for consumers and payers. And lastly, PCMA will be working collaboratively to ensure increased physician adoption of e-prescribing technology.

Mail-Service Pharmacy Option

PCMA is pleased that the Medicare Modernization Act recognizes the importance of providing seniors and disabled beneficiaries with access to the mail-service pharmacy option. Mail-service pharmacy allows for convenient access to prescription drugs at much more cost-effective prices. Without an effective mail-service pharmacy option, consumers' prescription drug costs would undoubtedly rise. According to PricewaterhouseCoopers, undermining the mail-service pharmacy option would increase prescription drug costs throughout the entire system by $97

billion between 2005 and 2014.[5] Similarly, a recent analysis by Milliman USA of a Michigan proposal to undermine the mail-service pharmacy option found it would raise the cost of prescription drugs in Michigan by 10 percent.[6]

Consumers are highly satisfied with mail-service pharmacies, according to a survey of nearly 14,000 mail-service pharmacy users nationwide. From the professionalism in customer service to outstanding accuracy in the drugs received by consumers, mail-service pharmacies receive high satisfaction marks of 95 percent or more.[7]

Confidentiality of Contracting and Drug Price Negotiation Information

While public disclosure of drug prices for consumer shopping is important, it is imperative that such disclosure not undermine competition by including confidential contracting and drug price negotiation information. Maintaining confidentiality in contracting and drug price negotiation is essential to preserving PBMs' ability to negotiate discounts for consumers and purchasers. Public disclosure of contract terms between PBMs, drug manufacturers, and retailers would dramatically alter the competitive landscape by giving competitors access to proprietary price negotiation strategies.

Policymakers have struck the right balance in the Medicare drug discount card program in assuring beneficiaries access to the right kind of information. In the drug card program, beneficiaries have had access to useful information that helps them compare drug prices at competing pharmacies. In addition, PBMs have provided CMS with numerous data related to drug pricing, rebates, and discounts. Importantly, CMS has protected the integrity of this information by embracing strict rules guaranteeing that such information remains confidential. Nonetheless, is critical that private and public purchasers alike keep contracting and drug price negotiation information confidential to prevent a loss of control over the use of the information. Without adequate confidentiality protections on the use of contracting and drug pricing

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[5] PricewaterhouseCoopers, "The Value of Pharmacy Benefit Management and the National Cost Impact of Proposed PBM Legislation," July 2004

[6] Milliman USA, "Potential Cost Impact of Michigan House Bills 4987, 5437 & 5438 on Purchasers of Prescription Drug Benefits," March 19, 2004.

[7] PCMA Patient Satisfaction Survey of Prescription Drug Benefit Programs, 2002.

information, competitors could obtain detailed drug pricing information and, ultimately, use it to set prices.

Numerous analyses have indicated cost increases associated with public disclosure of drug price negotiation information. During last year's Medicare debate, the Congressional Budget Office estimated that public disclosure of drug price negotiation information would increase the cost of the Medicare drug benefit by $40 billion over ten years and increase Medicare beneficiaries' part D premiums by more than five percent in 2006 alone. [8] PricewaterhouseCoopers has estimated that public disclosure of drug price negotiation information could increase prescription drug costs by 7 percent.[9] And the Federal Trade Commission's Office of Policy Planning has concluded that mandated disclosure of information "is more likely to undermine competition than promote it."[10]

Assure Appropriate Program Oversight & Beneficiary Protections, *Not* Micromanagement

PCMA believes the success of the new drug benefit will depend in no small measure on the active participation of PBMs. PCMA members have the knowledge, experience, and infrastructure that is essential for administering this new benefit. Given this record and the extremely short time frame for implementation of the new program, it is critical that the regulations not impose considerable new burdens or require significant changes in the way PBMs currently conduct their business in the commercial marketplace. Experience to date with the Medicare drug discount card program demonstrates the positive effect that competition can have on reducing drug prices. We expect to build on this experience in helping to administer the part D benefit.

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[8] Congressional Budget Office, "Cost Estimate of HR 1, Medicare Prescription Drug and Modernization Act, and S 1, Prescription Drug and Medicare Improvement Act of 2003," Page 15. July 22, 2003.

[9] PricewaterhouseCoopers, "The Value of Pharmacy Benefit Management and the National Cost Impact of Proposed PBM Legislation," July 2004.

[10] Federal Trade Commission's Office of Policy Planning, Bureau of Competition, and Bureau of Economics, Letter to California Assembly Member Greg Aghazarian, September 3, 2004.

One year from now, CMS will begin signing contracts with plan sponsors and preparing for the November 2005 beneficiary enrollment campaign – an ambitious schedule. Over the next year, organizations interested in sponsoring and/or partnering with other organizations to offer Medicare drug plans will need to prepare business plans, engage subcontractors, design benefit packages, develop formularies, negotiate prices with drug manufacturers, establish pharmacy networks that meet access standards, prepare marketing materials, prepare their bids, and update their electronic processing systems. While PCMA members are already engaged in this planning effort, until the final regulations are known, it is difficult to finalize plans. While PBMs can make some changes to formularies, pharmacy networks, and other aspects of benefits administration to meet Medicare program requirements, given the timeframes, it would be difficult to develop programs in the Medicare drug benefit that look and operate significantly different from the rest of PBMs' operations in the commercial marketplace.

Creating a Competitive Marketplace in Medicare

A key intent of the Medicare Modernization Act is to expand the choices and benefits available to beneficiaries. PBMs will help expand health plan options and benefits available to Medicare beneficiaries as likely partners with Medicare Advantage plans and possibly as stand-alone prescription drug plans. PCMA is encouraged by recent public comments from CMS Administrator McClellan that plans offering Medicare drug benefits would have access to cost-control tools such as formularies and tiered-payment structures. PCMA believes strongly that the preservation of these tools and other important PBM techniques, including the mail-service pharmacy option, will encourage maximum plan participation in the new drug benefit.

PCMA is also encouraged by recent comments from the CMS Administrator indicating that CMS is working to make insurance risk in the stand-alone benefit more predictable by providing re-insurance for catastrophic coverage; offering flexibility around risk corridors; making rules clear; and providing potential bidders with the best possible data so that they can make competitive bids. When combined with the availability of cost-control tools, predictable and limited-risk options will further encourage plans to offer benefits on a competitive basis.

Conclusion

PCMA and its member companies stand committed to do all we can to ensure the Medicare Modernization Act makes good on its promise to deliver more affordable prescription drugs to our nation's elderly and disabled. Over the next 18 months and beyond, we look forward to working with you, Mr. Chairman, the other Members of the Committee, your congressional colleagues, the Administration, seniors, and others to make the Medicare prescription drug benefit work as Congress intended and to build on the very best the private sector has to offer seniors and the disabled.

Mr. Chairman and members of the Committee, thank you for the opportunity to testify. I am happy to answer any questions you may have.

Questions from Senator Grassley

PBM Operations

The Committee is presently examining pharmaceutical benefit managers (PBMs) and how PBMs negotiate discounts and rebates with drug manufacturers. The Committee seeks to fully understand current drug pricing practices associated with PBMs. Greater transparency is necessary with regard to how PBMs negotiate with drug manufacturers, the kinds and levels of discounts PBMs receive, what PBMs provide to drug manufacturers in exchange for these discounts, and what PBMs provide to insurers and health plans. America's taxpayers deserve to know how they are affected by the concessions, rebates, and/or discounts PBMs receive from drug manufacturers. As Chairman of the Committee, I request responses to the following questions (if responses vary by drug manufacturer or by insurer or health plan, please be specific about the factors that affect differences):

As an association representing a number of competing PBMs, antitrust concerns prohibit the association from having access to competitive information involving our member's business practices. Therefore, we cannot fully answer portions of the questions below.

1. What services do PBMs provide to drug manufacturers? How are fees for these services determined?

   (See initial statement relating to competitive information)

   PBMs are the only organizations in the prescription drug supply chain dedicated to lowering the price of prescription drugs. This is done through negotiations with manufacturers to obtain price concessions on prescription drugs for their clients. Besides this primary activity any other activity with manufacturers varies by PBM and the individual PBMs would be in a better position to provide more information.

2. What services do PBMs provide to insurers and health plans? How are fees for these services determined?

   (See initial statement relating to competitive information)

   PBMs offer a wide range of services to insurers, health plans, and self insured employers including providing access to a pharmacy network, access to specialty pharmacy services, organizing a formulary based on the plans choices, negotiating discounted prices for those drugs from manufacturers, paying claims for pharmacy benefits, offering mail order access, disease management services, drug utilization review and others. Customers choose among the services PBMs offer

and select the benefit structure, including cost sharing structure, and all aspects of the formulary and formulary management.

As is the case with any market where there is competition for business, fees for services are determined based on the competitive market place and the effects of market forces. Plans have numerous choices and options in how they choose to have their pharmacy benefits managed. A recent DOJ/FTC report has found that the PBM industry has vigorous competition, which stimulates lower prices for beneficiaries and plans. [1]

3. How do PBMs negotiate price concessions, discounts and/or rebates with drug manufacturers? What factors are considered in establishing the size of the price concessions, discounts and/or rebates with drug manufacturers?

   (See initial statement relating to competitive information)

   At the discretion and authority of the plan sponsor, PBMs have the ability to leverage formulary placement of a drug to drive price concessions. For example, a drug that is one of a number of drugs within its therapeutic class would compete with the other drugs based on its safety, effectiveness and cost relative to the other competing products that are similarly indicated. The plan sponsor has ultimate authority to cover a drug and where that drug will be on the formulary. In addition, like many other companies in this country PBMs can obtain discounted pricing based on volume.

4. How do PBMs determine the share of the price concessions, discounts and/or rebates that is passed on to insurers or health plans?

   (See initial statement relating to competitive information)

   This is determined within the private contractual relationship that exists between the PBM and the customer insurers and plans. They may have arrangements that require full pass through of all concessions to insurers or they may choose to only keep a portion of the concessions. Since there are many different services PBMs offer to plans, plans may choose to emphasize one service over another and reflect this in the contract.

   Plans and insurers are very sophisticated purchasers and carefully consider the options they possess to provide pharmacy benefits to their enrollees. A plan can put out a competitive request for proposals based upon their set criteria and choose among a very competitive PBM industry to determine who is right for the job, or some plans have set up their own PBM affiliate to run their pharmacy benefit.

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[1] "Improving Health Care: A Dose of Competition" A Report from the Department of Justice, Federal Trade Commission. July 2004.

5. How many PBMs own a mail order pharmacy? How do PBMs determine who has access to the mail order pharmacy? How do PBMs determine drug prices for the mail order pharmacy?

   (See initial statement relating to competitive information)

   Most major PBMs own and operate mail-service pharmacies—a vital tool in making prescription drugs safer and more affordable for consumers. According to a 2003 study by the Government Accountability Office (1), PBM-owned mail-service pharmacies serving enrollees in the FEHBP program, had average prescription prices 27% below the average cash price of retail pharmacies for brands medications and 53% below the average retail cash price for generic medications. These discounted prices are available due to the tremendous efficiencies built into mail-service pharmacies sophisticated use of pharmacy experts and technology to achieve tremendous economies of scale and high degrees of accuracy. As with all aspects of the PBM business, vigorous marketplace competition drives PBMs to offer maximum value to their clients in order to retain and build business.

6. How many PBMs manage any drug discount cards? How do PBMs determine who has access to the drug discount cards? How do PBMs determine what discounts are available with the cards?

   (See initial statement relating to competitive information)

   Many if not all of PCMA member companies have a commercial drug discount card or offer a Medicare drug discount card. Most PBM commercial cards are available to all adults.[2] The Medicare drug card provides access to Medicare beneficiaries who do not have employer sponsored coverage or Medicaid.

   (See answer to #3) Formulary placement is not as effective in a drug card since drug cards typically provide a discount on most outpatient drugs. There can be volume discounts and discounts taken off the usual and customary price that a pharmacy may charge a cash paying individual. This price can vary by pharmacy and locale since the pharmacy sets its own usual and customary price.

7. How do PBMs determine what drugs are selected for inclusion in formularies, preferred lists, or other incentive programs? Are these incentives known by the insurers and health plans with whom PBMs contract?

   (See initial statement relating to competitive information)

   Inclusion of drugs for inclusion on a formulary is at the discretion of the plan sponsor. PBMs can adjust the formulary based on their customer needs and price

[2] See GAO Report 03-912. "Prescription Drug Discount Cards- Savings Depend on Pharmacy and Type of Card." Sept. 2003.

that product accordingly. PBMs have contractual relationships that they negotiate with their customers. All activities that PBMs undertake on behalf of their customers follow this contract, which is willingly engaged in by both the plan sponsor and the PBM.

Plans and insurers are very sophisticated purchasers and carefully consider the options they possess to provide pharmacy benefits to their enrollees. A plan can put out a competitive request for proposals based upon their set criteria and choose among a very competitive PBM industry to determine who is right for the job, or some plans have set up their own PBM affiliate to run their pharmacy benefit.

8. How does PBMs' use of generic drugs in retail and mail order pharmacies compare with industry standards? What incentives do PBMs provide for using generic instead of brand name drugs?

   (See initial statement relating to competitive information)

   Encouraging the clinically appropriate use of generic drugs is a primary cost-saving tool of PBMs. PBM clients typically select benefit design options that encourage their enrollees to use generics. For example, some plans make generics available at lower copayment/coinsurance amounts than their brand name counterparts. According to a 2004 study by Harvard University economists recently published in Health Affairs (2), patterns of generic drug dispensing and substitution are comparable at mail-service and retail pharmacies, once differences in the types of drugs consumers seek at these two types of pharmacies is taken into account. In the retail pharmacy setting, consumers typically seek prescriptions for acute conditions, whereas mail-service pharmacies are more likely to dispense prescriptions treating chronic conditions. The Harvard economists assert that this "therapeutic mix" adjustment is essential to allowing direct comparisons between PBM mail-service pharmacies and retail pharmacies. The analysis examined 670 million prescription drug claims processed by five large PBMs during the first six months of 2003. The analysis compared generic drug dispensing and substitution patterns at PBM-owned mail-service pharmacies versus retail pharmacies. Among the key findings from the Harvard Business School analysis is that the generic substitution rate for retail pharmacies and PBM mail-service pharmacies is essentially the same. For retail pharmacies, the generic substitution rate is 92 percent. For mail-service pharmacies, the generic substitution rate is 93 percent. Generic substitution rate refers to how often a generic is dispensed by a pharmacy when a generic alternative to the brand is available. The authors suggest that mail-service pharmacies may have more success in substituting generics for brands due to the generally longer time mail-service pharmacies have to fill a prescription. The Harvard study also finds that the generic dispensing rate for retail pharmacies and PBM mail-service pharmacies is essentially the same. For retail pharmacies, the generic dispensing

rate is 40 percent. For PBM mail-service pharmacies, the generic dispensing rate is 39 percent.

9. How effective do you think PBMs will be in negotiating discounts on behalf of Medicare beneficiaries under the new Medicare drug benefit?

   PBMs have a proven track record of saving money for their customers. In fact many of these existing customers include seniors. A CMS study estimated 65 percent of Medicare beneficiaries who have prescription drug benefits through employer and union-sponsored retiree health plans use a PBM.[3] The value PBMs provide has been substantiated by numerous studies including—

   - According to a recent PricewaterhouseCoopers study, PBMs drive down the cost of prescription drugs for their clients on average by 25 percent – or the cost clients would otherwise incur if they chose not to contract with a PBM. Depending upon the level of pharmacy benefit management sought by an employer, health plan, Taft-Hartley union plan, or state and federal government, the savings can range from 15 percent to as much as 40 percent.

   - The Congressional Budget Office found that given appropriate cost containment tools, PBMs could save Medicare beneficiaries up to 30 percent. [4]

   If the tools of the industry are allowed to function for the Medicare population as they currently function for other payers, measuring the impact should not be difficult. While manufacturers set the prices of prescription drugs—not PBMs—the tools used by PBMs reduce these costs for beneficiaries.

10. How can Congress measure the impact or value of these negotiations for the Medicare program and for Medicare beneficiaries?

    PBMs are achieving savings in the Medicare drug discount card program of 17-35 percent of the retail price, as well as the documented savings measured in the past by a number of different entities including the CBO, GAO and CMS.

    With flexibility provided for PBM tools to work for the Medicare population, I am confident the savings will be achievable and measurable.

Questions from Senator Baucus

[3] Centers for Medicare & Medicaid Services, "Study of Pharmaceutical Benefit Management," Conducted by PricewaterhouseCoopers, June 2001

[4] "Issues in Designing a Prescription Drug Benefit for Medicare." Congressional Budget Office. October 2002.

1. Mr. Merritt, at the hearing I asked you to outline what additional information is needed before PBMs would be willing to commit to participating in the new drug benefit, either as a stand-alone at-risk plan or a fallback plan. Since we were at the end of our time, I felt that you did not have an adequate opportunity to answer this question. Could you please do so in writing?

   PCMA believes that there will be widespread participation by PBMs in the Part D program. Since I am representing a trade association, we do not have access to competitive information such as our individual member's business plans and do not know in what manner they plan to participate.

   It is important to note that there are many other factors that go into the decision of becoming a stand alone plan besides taking risk. Primarily, the tools of the industry have to be protected, such as formulary development activity, DUR, etc. Also, many PBMs do not have brand recognition or label directly with the public, requiring an enormous investment in marketing. Combined with a short timeframe to submit bids to CMS, there are a lot of challenges beyond risk that need to be dealt with.

   We do know PBMs are looking closely at stand alone plans and have provided comments and input to CMS. It is important to realize that the PBM industry is not accustomed to taking risk but are weighing their options and are very interested in seeing the final rule.

2. Mr. Merritt, the 2003 Medicare bill sought to balance the tension to between providing access to medically-necessary drugs and appropriate cost containment. In your respective opinions, do the Title I regulations appropriately strike this balance?

   PCMA has provided comments to CMS on the proposed rules that emphasize the need for the final rule to achieve this balance. The only way this balance can be accomplished is by preserving the flexibility of PBM tools to allow the PBM industry to work for Medicare beneficiaries in the same manner it has successfully worked for private and public sector plans. It is critical CMS carefully consider this balance in finalizing the proposed rule to ensure a successful Part D program.

Questions from Senator Hatch

Background

There are more than one million dual eligible beneficiaries as well as additional elderly beneficiaries with mental illnesses who require psychotropic medications. The scope and impact of severe and persistent mental disorders and the cost of treatment is indisputable. The U.S. Department of Health and Human Services in 2003 recognized that four of the top ten leading causes of disability in the United States were indeed psychiatric in origin.

It is clear that the Medicare conferees who drafted the MMA were concerned about ensuring that all Medicare beneficiaries with special needs have access to their medications under Part D. The language in the final conference report is unequivocal. "It is the intent of the conferees that Medicare beneficiaries have access to prescription drugs for the treatment of mental illness and neurological diseases resulting in severe epileptic episodes under the new provisions of Part D. To fulfill this purpose the Administrator of the Center for Medicare Choices [sic] shall take the appropriate steps before the first open enrollment period to ensure that Medicare beneficiaries have **clinically appropriate access** to pharmaceutical treatments for mental illness, including but not limited to schizophrenia, bipolar disorder, depression, anxiety disorder, dementia, and attention deficit disorder/attention deficit hyperactivity disorder and neurological illnesses resulting in epileptic episodes. (Emphasis added) (Sec. 923 of the Joint Explanatory Statement of the Medicare Conferees, Nov. 21, 2003, p. 321).

The Report of the President's New Freedom Commission on Mental Health cites the critical importance of Medicare and Medicaid Reform to improving the quality and accessibility of mental health service delivery through support of evidence-based treatments. On August 20, 2004, CMS itself published a paper entitled "Psychotropic Medications: Addressing Costs without Restricting Access." The paper stressed that despite the current economic conditions and pressures on states, states have effectively implemented alternative cost management techniques related psychotropic medications without restricting access to specific medications. The paper cites several examples of states as models, including Missouri, Texas and Pennsylvania that have reduced the amount spent on psychotropic medications while not limiting access.

Question for Pharmaceutical Care Management Association

1. CMS requested comments regarding any special treatment, for example, offering certain classes of enrollees an alternative formulary that accounts for their unique medical needs as well as suggestions regarding the particular special populations for whom CMS may want to make allowances. If there is a alternative flexible formulary available for special needs populations, has PCMA thought about payment alternatives or other incentives to encourage Prescription Drug Plans (PDPs) to offer the an alternative formulary for these populations?

   PBMs recognize the importance of special populations receiving the medications they need. Currently in the commercial market, mental health drugs are widely covered due to the unique needs of the population and variable effects these treatments can have on an individual by individual basis. They are often excluded from any step therapy requirements as well to ensure the needs are met.

Senate Finance Committee Hearing on Medicare Regulations
Senator John D. Rockefeller IV
Statement for the Record
September 14, 2004

Mr. Chairman, thank you for holding this hearing on implementation of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. I really wanted to attend this hearing, but, because the Intelligence Committee is considering the nomination of Porter Goss all day today, I will not be able to join you. I do want to convey, however, how important I think it is that this Committee maintain a keen focus on implementation of this new law; not just today prior to the publication of final regulations, but throughout the process.

This new law will impact nearly 40 million seniors and disabled Americans, and, in my opinion, many of them stand to lose more than they will gain. Our Committee must be poised to recognize problems early, and to move forward with legislation to fix those problems without delay. We cannot allow partisan politics or turf battles to deter us from our mission of making public policy decisions that benefit seniors, one of the most vulnerable segments of our population.

What I have already seen of implementation has only deepened my opposition to the Medicare law. Both the drug discount card program and the oral anti-cancer demonstration project have been disappointing, particularly in my home state of West Virginia. With the prescription drug discount cards, this Administration put pharmaceutical companies ahead of seniors. We have 41 different Medicare-approved drug discount cards in West Virginia. Many of my colleagues will argue that we have so many cards so that seniors have choices. But this isn't about senior choice; it's about lining the pockets of pharmaceutical companies with even greater profits.

How is a senior supposed to choose from 41 different cards, especially when the companies offering the discount cards can change their drug prices weekly or stop offering discounts on particular drugs altogether? The seniors in my state are frustrated and confused with the drug discount card program. If this program was really about senior choice, drug companies wouldn't be allowed to flip-flop on drug prices and discounts weekly while seniors are locked into one Medicare-approved discount card for a whole year. If we were serious about giving seniors choices and truly lowering the cost of prescription drugs would allow Medicare to negotiate directly with drug companies and allow seniors to reimport prescription drugs from Canada.

On Saturday, September 11, the *New York Times* reported that less than 4,000 Medicare participants are enrolled in and fewer than 7,000 have submitted applications for the Medicare Section 641 demonstration project. As a primary author of the legislation upon which this demonstration is based, I am extremely dismayed over these enrollment figures. West Virginia has the 4th highest cancer death rate in the nation, yet my constituents remain largely unaware of this demonstration.

CMS has not done an effective job of outreach. When considering this Administration's earlier outreach efforts to announce the new Medicare law and the drug discount card program, it is difficult to understand why similar outreach efforts have not been undertaken to announce this demonstration project. Earlier this year, the Department of Health and Human Services sent a flyer to all Medicare beneficiaries with information about provisions in the Medicare law, even though the law will not go into effect until 2006. According to the Government Printing Office, this flyer cost taxpayers $10 million – $3.2 million in printing costs and $6.8 million in mailing costs. HHS spent an additional $9.5 million on television ads announcing the new law, again despite the fact that the law will not go into effect until 2006. The oral anti-cancer demonstration project, which could mean access to life-saving treatments for so many seniors, should receive the same level of attention.

Unfortunately, the regulations published by CMS on July 26, 2004, have done little to mitigate my opposition to this new law. In fact, given my experience with the first two programs to be implemented under the so-called Medicare Modernization Act, I am extremely worried about implementation of Part D in 2006. Instead of taking decisive action on the proposed rules, CMS has been extraordinarily vague and has punted making a decision on several important issues.

One issue that I have been particularly concerned about is retiree coverage. Employer-sponsored retiree coverage represents deferred compensation for retirees, a thank you for years of hard work and service. Yet, the Congressional Budget Office estimates that as many as 2.7 million retirees will lose their employer-sponsored prescription drug coverage as a result of the new Medicare law. Recent press reports indicate that the number of retirees losing coverage may be even higher. CMS should have used the regulatory process to implement a clear standard that protects retirees. Instead, CMS has taken an "options" approach to the regulatory process. This type of approach is unfair to the millions of retirees who have worked hard for the benefits they now enjoy. These benefits are not optional to them and we should not take an arbitrary approach toward protecting these benefits.

In closing, Mr. Chairman, I would like to mention one final issue – the recently announced Medicare Part B premium increase. Never in the history of the Medicare program has the annual dollar increase in premiums been this great. The Administration announced this enormous increase at a time when many West Virginia seniors are struggling to balance skyrocketing prescription drug costs with their transportation, food, and home utility needs.

Twenty-percent of next year's $11.60 premium increase will go directly to HMOs. Medicare HMOs don't come to West Virginia and West Virginia seniors should not bear the burden of paying for them. Our seniors deserve better. That's why I have introduced legislation to limit the 2005 Medicare premium increase to an amount equal to the Social Security cost of living adjustment (COLA) for next year, which is expected to be around 3% when it is released in mid-October. I hope my colleagues will join me in supporting this important legislation.

I thank the Chairman.

Statement of Gerald M. Shea, Assistant to the President for Government Affairs
American Federation of Labor and Congress of Industrial Organizations
Before the Senate Finance Committee
September 14, 2004

Thank you for the opportunity to offer our perspective on the proposed rules implementing the Medicare Prescription Drug Benefit. On behalf of the AFL-CIO's 13 million active members and more than 3 million retirees, I will focus my comments today on the regulations implementing the employer subsidy.

The changes in Medicare enacted last year will have enormous and far-reaching effects on the medical and prescription drug benefits provided to our nation's elderly and disabled. Roughly one in four Medicare beneficiaries currently receives prescription drug coverage from their former employer – representing the single largest source of such coverage for Medicare beneficiaries.

In enacting the employer options and subsidy, Congress sought to encourage employers to retain prescription drug benefits for their retirees. The preservation of employer-sponsored prescription drug benefits is clearly in the best interests of retirees and consistent with the fact that these benefits represent deferred wages over a lifetime of work. But it is also in the best interest of the Medicare program; sharing with employers the cost of prescription drug coverage for millions of beneficiaries better serves Medicare's financial health.

The provisions outlining employer options for continuing to provide prescription drug coverage are complex and represent mostly unchartered territory. While the statute was prescriptive in certain respects, it also left to the Administration broad authority to implement many of the provisions, particularly with regard to the employer subsidy. While the proposed rules published last month fail to provide clear guidance (and on some issues, no guidance at all) to employers and retirees on the options they will have and the standard employers must meet in order to qualify for the federal subsidy, our hope is that the final rules will do both.

Overall, we fully support the Department's objectives, as stated in the proposed regulations, "to take into account as much as possible the needs and concerns of plan sponsors, consistent with necessary assurances that Federal payments are accurate and in accordance with statutory requirements, that the interests of retiree-beneficiaries are protected, and that employers do not receive "windfalls" consisting of subsidy payments that are not passed on to beneficiaries."[1]

However, we have serious concerns that the proposed regulations may tilt too far in favor of the needs and concerns of plan sponsors and offer too few protections for the retirees whose coverage Congress has sought to preserve with this federal subsidy. While CMS Director Dr. McClellan has said the employer provisions will result in retirees spending

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[1] 69 Fed. Reg. page 46737 (August 3, 2004)

less for prescription drugs and in some cases much less, we fear that the regulations potentially allow for even those retirees who retain coverage to be made worse off.

Already, we are seeing employers "book" the anticipated value of the subsidy they will receive as non-taxable income. A Wall Street Journal article published in March lists projected savings claimed by 18 large companies, ranging from $2 million to $1.4 billion. Yet we also know from recent contract negotiations and from published survey data that employers are pressing their retirees to pay a growing share of drugs costs each year.

As we continue our review and analysis of the proposed regulations, the AFL-CIO has three overarching areas of concern. First, the test for actuarial equivalence should not allow for significant cost shifting. In the proposed rules, CMS has outlined three options for determining actuarial equivalence. The "single prong" test would look only at the gross value of the benefit, regardless of financing. This test is totally unacceptable, since it would result in massive cost shifting, and in CMS's own words, would allow employers to contribute nothing yet still get the subsidy. The other two proposed tests – the "no windfall" test and the "two-prong" test – are preferable to the first test, since they take into consideration the amount the employer is paying toward coverage, yet both also have the potential to allow employers to shift costs to retirees and still receive the federal subsidy.

We understand the difficult calculation that CMS must make in establishing the actuarial equivalence standard – set the bar too high and employers may choose to drop coverage rather than meet the standard; set the bar too low and employers may interpret that as a signal to significantly reduce the coverage they now provide. To be consistent with the intent of the law, CMS must require employers to provide at least as much financing for retiree drug coverage as they will get from the subsidy. And in order to prevent employers from using the actuarial equivalence standard as an excuse to significantly reduce the coverage they now provide – even with the financial assistance of the subsidy – CMS must adopt and enforce strong retiree protections.

One such protection, and a key area of concern for us, would be to ensure the subsidy is used to preserve retiree benefits and not used simply to improve the employer's bottom line or for other non-health care uses. As you know, the statute does not include a maintenance of effort, or even maintenance of cost provision, nor did we advocate for such a requirement in the legislation. Until Congress enacts legislation that will meaningfully address crippling health care cost hikes, we believe such a position is untenable. However, the statute explicitly and directly ties the subsidy to the provision of prescription drug coverage, reflecting, we believe, Congress' intent that the subsidy be used to offset costs for both the employer and the retiree. Employers should demonstrate that the subsidy is allocated to health benefits according to the financing of those benefits. At a minimum, CMS must require employers to report to retirees and unions the value of the subsidy received, if the public is to have any ability to measure the effect of the subsidy on preserving retiree health benefits. To have much effect, such notices must be as contemporaneous as possible with the receipt of subsidy payments.

Finally, the regulations must include safeguards to ensure employer coverage meets the actuarial equivalence test in both design and practice, and in this area, we have several additional concerns. First, because the actuarial equivalence test is applied to the average of all retiree health plans offered by an employer, there is the potential for significant variation in the plans and, by extension, the use of different plan designs to encourage higher cost beneficiaries to enroll in Part D plans.

In addition, the plan is measured according to projected benefits as opposed to benefits received, when projections can clearly be unrealistic. For example, a plan sponsor may provide full coverage for prescription drugs for organ transplant patients, yet very limited coverage for drugs used to treat hypertension and diabetes. At the end of the plan year, actual spending on organ transplant drugs may be zero, while many more retirees required treatment for hypertension and diabetes. CMS has not outlined a process for reconciling the projected and actual spending, an important consideration to ensure appropriate use of the subsidy.

Despite these potential abuses, the proposed regulations do not include a process for retirees to challenge an employer's attestation that its plan is actuarially equivalent, nor does it require transparency in regard to plan sponsors' attestations or the underlying assumptions and projections. It would seem wise to include such requirements for transparency and attestation challenges in order to empower retirees and other interested parties to act as guardians of this new federal subsidy.

We have many other concerns in addition to these primary ones. They include holding retirees harmless from late enrollment penalties if their employer's actuarial equivalence attestation proves to be inaccurate. In addition, plan sponsors will be subject to unrealistic timeframes for designing a benefit, attesting to actuarial equivalence and notifying retirees of their plan options – all of which may occur without clear and final guidance from CMS or adequate information on the availability of commercial prescription drug or Medicare Advantage plans.

We would commend Dr. McClellan and the CMS staff for their outreach and willingness to discuss concerns of workers and their unions. We will be offering more detailed, written comments on the proposed regulations, as we seek to maximize the benefit for our members.

However, we continue to believe the law enacted last year did not go far enough in providing incentives for employers to retain retiree drug coverage. The True Out of Pocket provision has the effect of discriminating against beneficiaries with retiree health benefits and the employers who continue to provide them in the face of escalating health care costs. And the additional funds provided for the employer subsidy in the conference agreement -- $18 billion to make the subsidy tax-free – provided absolutely no additional benefit to non-taxable entities such as public sector employers and multi-employer plans that provide retiree health benefits.

At the same time, HMOs were provided billions of dollars in excessive overpayments in the legislation and beneficiaries were left with an inadequate benefit. While we appreciate the Department's efforts to limit the effect of this legislation on retiree coverage through regulation, the fact is that the True Out of Pocket definition in the law again favors private plans over retirees. Indeed, the fact that this legislation puts private plans' interests over that of retirees has manifested itself already - two years before the drug benefit is even implemented. Just last week, CMS announced the largest increase in the Part B premiums since the enactment of the program, which is largely a result of the provisions in this legislation. Our members, like the public at large, are saying this law needs to be overhauled, in order to put beneficiaries ahead of HMOs and drug companies.

Despite the limits of the legislation, the Administration has broad authority to implement the employer subsidy. Establishing the requirements employers must meet to qualify for the subsidy can either exacerbate or mitigate the harmful provisions of the underlying statute – making the number of retirees who are helped rather than hurt relatively better or worse. CMS has stated in the proposed regulations that the federal subsidy has the potential to stem the erosion of retiree health benefits. We believe this goal is laudable and we urge the Administration to issue final regulations that achieve that goal and address the concerns we have raised today

Questions from Senator Grassley

1. In your testimony, you note that there is no process through which a retiree could challenge an employer's attestation that its plan equals the value of the Part D benefit and thus qualifies the employer for the retiree drug subsidy. Do you have specific ideas about how such a process could be crafted?

Response: At a minimum, CMS should consider the Internal Revenue Service (IRS) notice and comment rules governing plan sponsors' requests for determination letters as to the qualification status of retirement plans as one possible approach that could be adapted to the Medicare Modernization Act (MMA) Under these determination letter rules, plan sponsors must notify interested parties (e.g., plan participants and their collective bargaining representatives) that the sponsor is filing a determination letter application, that interested parties may request related documents, and that interested parties may file comments with the IRS on the application within specified time periods. Interested parties may then file formal comments with the IRS, which become part of the official administrative record.

A stronger alternative to this approach would be to develop a challenge process that tracks the process for employers to challenge a subsidy determination, as outlined in the Preamble to the proposed regulations (69 Fed. Reg. 46749). That appeals process would include three steps for review of subsidy determinations: a request for an informal written reconsideration by CMS; an informal hearing before a CMS hearing officer; and a review by the Administrator.

Allowing retirees and their representatives to challenge an attestation would be consistent with CMS's goal of protecting against employer windfalls. CMS states in the Preamble, "Some observers have argued that the forces in a competitive labor market, collectively bargained contracts, and constraints on changing state, local and other public sector retiree health plans obviate the likelihood of windfalls. We have serious reservations about the adequacy of such forces in precluding the existence of any windfalls without significant additional monitoring by Medicare **or others** to assure that the benefit subsidy payments are passed on to augment benefits received by retirees." (69 Fed. Reg 46741, emphasis added).

The ability to challenge an employer's attestation will depend in large part on the availability of information regarding the employer's attestation and underlying assumptions, as well as information regarding subsidy payments to employers for the "actuarially equivalent" coverage provided. Absent this information, retirees and their representatives will not have the information necessary to know whether a challenge is warranted.

Questions from Senator Baucus

1. Mr. Shea, what is the best way to define actuarial equivalence? What is the best way to ensure that existing retiree coverage is maintained and that the subsidy is

only paid to employers that provide coverage equal or greater than the standard Medicare benefit?

Response: In our view, the best way to ensure that existing retiree coverage is maintained is to maximize the incentives available to employers to retain that coverage. Unfortunately, the True Out of Pocket provision in the statute will have the effect of limiting those incentives by discriminating against beneficiaries with retiree health benefits and the employers that continue to provide drug coverage in the face of escalating costs.

Furthermore, the structure of the statute promotes cost shifting to retirees. Employers are allowed to shift to retirees the difference between what they are currently paying for retiree drug coverage and the amount necessary to meet actuarial equivalence. If the employer reduces benefits by shifting this extra cost to retirees, the employer is not disadvantaged, because the employer's subsidy under Part D is based upon the total spending for prescription drugs paid by both the employer and the employee.

Even with the structural limits of the statute, the Administration has broad authority to implement the employer subsidy. In particular, the way in which CMS defines the standard employers must meet to qualify for the subsidy will have an enormous effect on whether or not the subsidy helps preserve retiree benefits as Congress intended. We believe the ability to shift costs to retirees can only be blunted by adopting the highest rational standard for actuarial equivalence.

In our comments filed with CMS, we submitted the following recommendations regarding the actuarial equivalence test that we believe are consistent with CMS's goals.

- CMS should adopt the Two-Prong Test for actuarial equivalence, which requires the portion of the prescription drug plan financed by the employer to be at least equal to the portion of the Part D benefit that is financed by Medicare. Only this test is consistent with the letter and intent of the MMA to provide for alternative drug coverage that is actuarially equivalent to the standard Part D benefit. The comparison of the employer plan to the Part D benefit should be based on the benefits provided, not the cost.

- All of the other standards described by CMS in the Preamble to the proposed rules could penalize retirees covered under a retiree drug plan and should be rejected. The Single Prong Test, the Single Prong/No Windfall Test, and the two versions of the Two-Prong Test that permit the employer to limit its contribution to the average subsidy amount it would expect to be paid from Medicare could all require a retiree to pay more for her drug coverage than she would if she were covered under a Medicare Part D prescription drug plan.

- In order to achieve the policy goals of Congress and CMS, the regulations should prohibit windfalls to employers. In no instance should the subsidy exceed the subsidy an employer provides for the retiree prescription drug benefit.

- The maximum potential subsidy an employer may receive is $1,330 (28% of costs between $250 and $5,000). This may exceed the employer's contribution even if the

standard is set at the net actuarial value of the Medicare Part D benefit (valued by CBO at $1,200 in 2006).

- Other tests being considered by CMS would allow for even greater windfalls to an employer. The Single Prong (or Gross Value) Test would allow for enormous windfalls to employers since it would permit an employer to pay nothing toward the drug benefit and still collect federal subsidies. This option has been roundly criticized in the press, is inconsistent with the intent of Congress, and would undermine the integrity of the Medicare drug program.

- CMS also should reject the Single Prong/No Windfall Test that would limit the amount of the subsidy the employer receives to the amount paid by an employer for retiree drug coverage. This test would allow an employer to effectively pay nothing toward retiree coverage (once the federal subsidy is taken into account) and massively shift costs to retirees at the same time.

- Where the anti-windfall protections would prohibit an employer from claiming the largest possible retiree drug subsidy payable under the law, CMS should provide a mechanism permitting the plan sponsor to claim the larger subsidy, so long as it passes through to the affected retirees the value of the subsidy exceeding the employer contribution in the form of improved prescription drug benefits.

2. Mr. Shea, how are retiree health benefits negotiated? What impact will the new drug benefit have on your members under each of the options for defining actuarial equivalence that CMS has outlined in the proposed rule?

Response: Thirty to forty thousand collective bargaining agreements are negotiated every year, and provision of healthcare benefits for active and retired workers is an issue in almost all of them. Employers are required to bargain about healthcare benefits for active workers, and about the healthcare benefits that active workers will receive when they retire. However, they are not required to bargain about healthcare benefits for workers who have already retired

Moreover, unlike pension benefits, the healthcare benefits of retired workers are not automatically vested by operation of law. Therefore, the employer can modify retiree health benefits unless the union has convinced the employer to guarantee them by contract. Employers rarely agree to such commitments, and many reserve the right to modify or terminate the healthcare benefits of their retirees at any time, regardless of the period of the contract. Consequently, even at unionized workplaces, employers will have considerable power to take the provisions of the new Medicare law into account and change healthcare benefits previously negotiated for their retirees.

As stated above, employer response to the regulations will depend in large measure on the way in which actuarial equivalence is defined, as well as other factors, including the nature of contract negotiations. The decision to provide coverage that qualifies for the subsidy versus coverage that supplements or "wraps around" the Medicare Part D benefit will likely be affected by the employer's average per person spending for prescription

drug coverage. If the per person average is less than $2,250 per year, the employer may choose to supplement the Part D coverage and assist retirees with expenses not covered under Medicare Part D (i.e., the premium, deductible and co-insurance). However, if the employer's per person average is above $2,250, a supplemental benefit is a less attractive option, since the employer that decides to assist with the retiree's co-insurance would be liable for drug expenses effectively without limit – paying for a "donut hole" that doesn't end, due to the effect of the True Out of Pocket definition.

In considering other employer options under the MMA to become a Medicare Advantage (MA) or Prescription Drug Plan (PDP) – employers will presumably take into consideration the ease of becoming such a plan and the relative value of the reimbursement for those plans (compared to the employer subsidy for actuarially equivalent coverage). In addition, the decision to contract with a PDP or MA plan will depend at least in part on the availability, design and cost of those plans in areas serving the employer's retiree population.

Questions from Senator Rockefeller

1. At the August 19 public forum on retiree coverage, several concerns were raised about transparency surrounding the employer attestation process. What type of employer disclosure standards do you feel would be appropriate to make sure employers are actually meeting the actuarial equivalence standard (once it is defined)? What type of appeals process do you think should be established?

Response: In order to protect the integrity of the program, CMS must adopt measures to ensure that the implementation and administration of the subsidy payments to employers are transparent to retirees, their bargaining representatives and the public. Such requirements are essential to achieving Congress's and the President's objectives that these substantial new subsidy payments be used to preserve and possibly improve retiree drug coverage, that no windfalls be created and that costs to the government be minimized.

We recognize that CMS has resource limitations on the extent to which it can review the accuracy of employer Attestations and claims for a subsidy. CMS also has broader responsibilities to insure the integrity of the entire Medicare program, which may require vast resources to audit managed care plans and PDPs. By opening the employer subsidy process to scrutiny from retirees and their unions, CMS can allow them to serve as watchdogs with respect to employer retiree drug benefits.

In our comments filed with CMS, we submitted the following recommendations to provide greater transparency and to ensure the integrity of the program:

- In general, all reporting and disclosure should be made public in a manner that is timely and permits easy access to the information.

- A Plan's Sponsor's "Attestation" of actuarial equivalence should include the assumptions and methods used to determine the plan's actuarial equivalence and should be available for public inspection shortly after it is filed with CMS. In

considering the appropriate form for this disclosure, CMS should look to reporting and disclosure rules of the Employee Retirement Income Security Act (ERISA), with which most plan sponsors and their professional advisors are extremely familiar.[1] In particular, the annual Form 5500 Schedule B can be a useful model for disclosure formats, although we would oppose relying on the time frames required for ERISA disclosures, because the significant time lags in ERISA reporting typically mean that the information provided is out of date.

- If the public is to have any ability to measure the effect of the subsidy on preserving retiree health benefits, CMS must at a minimum require employers to report to retirees and unions the value of the subsidy received, as well as the aggregate claims data used to make the subsidy payments. To have the desired effect, such notices must be provided as soon as possible after the conclusion of the calendar year.

- Retirees and their unions should have the right to an appeals process regarding employers' actuarial equivalence attestations and subsidy amounts received. (See response to Senator Grassley's question, above, for details on how such an appeals process could be structured.)

Additional disclosure requirements would further protect retirees from being made worse off as a result of the employer subsidy:

- The employer must be required to notify retirees who are being offered a drug benefit that is inferior to the standard Part D benefit. This situation could arise in at least two situations: first, if CMS adopts an actuarial equivalence standard that permits the actuarial value of the benefit not financed by a retiree to be less than the value of the standard Part D design not financed by a retiree; and second, if CMS adopts a "plan" definition allowing sponsors to average inferior contribution levels or benefit designs for some retirees with superior contribution levels or benefit designs for other retirees and still satisfy the regulatory standard for actuarial equivalence. Requiring such a notice not only will provide retirees with necessary information for deciding among their coverage options, but also influence the coverage sponsors offer to retirees. Because employers likely will not want to send out notices informing retirees that their coverage is inferior even though it satisfies the test of average actuarial equivalence, some employers may improve coverage for affected segments of retirees. We believe this will promote the core objectives of the statute.

- The regulations should require employers that offer a supplemental benefit that combines medical and drug coverage to offer a separate medical benefit that allows retirees to retain those benefits even though they may enroll in a Medicare Part D plan. This is particularly important for retirees who are offered drug benefits that are inferior to the standard Medicare Part D prescription drug benefit (i.e., the benefits do not constitute creditable coverage or the value of the benefit offered is less than the

[1] Only private-sector and multiemployer plans are governed by ERISA. State and local government plans are not. However, the same principles of reporting and disclosure and open access to information are familiar to governmental plans due to the public environment in which they operate.

value of the standard Part D benefit). In the event CMS does not impose this requirement on employers, it should require employers to notify retirees that leaving the employer's plan to enroll in a Medicare Part D plan will automatically eliminate their employer-provided supplemental medical coverage, as well.

- Employers should provide a separate notice to individuals that they have creditable coverage, in order to ensure retirees are aware of their options and can make timely decisions necessary to avoid the late enrollment penalty for the Part D benefit. For example, providing notice as part of other disclosures, such as ERISA summary plan descriptions, is not sufficient.

COMMUNICATIONS

ANÍBAL ACEVEDO-VILÁ
COMMONWEALTH OF PUERTO RICO

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AGRICULTURE
SMALL BUSINESS
RESOURCES

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September 13, 2004

The Honorable Charles Grassley
Chairman
Senate Finance Committee
219 Dirksen Senate Office Building
Washington, D.C. 20510

Re: Comments for Senate Finance Committee Sept. 14, 2004 Hearing on CMS Regulations; Options for defining regions for Medicare Advantage regional plans and Prescription Drug Plans under the Medicare Modernization Act of 2003

Dear Chairman Grassley:

As the Resident Commissioner of the Commonwealth of Puerto Rico, I appreciate the opportunity to offer these comments for the record regarding the proposed definition of regions for new Medicare Advantage (MA) regional plans and for the prescription drug plans (PDPs).

It is my understanding that Research Triangle International (RTI), a contractor for the Centers for Medicare and Medicaid Services (CMS) has presented a number of multi-state regional options that included Puerto Rico. After consulting with a broad cross section of healthcare providers in Puerto Rico including physicians, hospitals, academics, insurance carriers and the Commonwealth government, there is a unanimous agreement that none of the RTI's proposals for either the MA plans or the PDPs (or both) account for the unique circumstances of beneficiaries living in Puerto Rico including differences in actual drug spending, average per capita income, language and other cultural considerations.

There is a strong agreement that the multi-state regional options would seriously undermine the viability of the Medicare Part D program in Puerto Rico. Plans and providers currently active in Puerto Rico are not likely to participate under such a structure if implemented in the Commonwealth, and more importantly, Puerto Rico's beneficiaries would have little incentive to opt into the Part D program.

There is also strong agreement among the health care industry in Puerto Rico that to ensure the 601,773 Medicare-eligible individuals residing in Puerto Rico do have the opportunity to participate in programs created by the MMA, it is essential the Secretary exercise his authority to establish a region for the Commonwealth of Puerto Rico. There are a greater number of eligible individuals living in Puerto Rico than the number of eligibles living in 24 states.

Each of the multi-state regional options presented to CMS, combined Puerto Rico in a region with Florida. Florida may be the state that is geographically closest to Puerto Rico, but significant differences exist between the two jurisdictions in terms of their economies, health care systems and infrastructure, and patient demographics, among other factors. As a result, there is no substantive rationale for combining these two disparate areas into one region.

For example, Florida's cost structure is significantly higher than Puerto Rico's. The estimated payment rate for Puerto Rico is $507.09 per month, the lowest in the nation. In contrast, Florida's estimated payment rate of $712.52 is among the top 10 in the United States. By RTI's analysis, Florida residents are among the least healthy in the nation; residents of Puerto Rico are in roughly average health compared to residents of the states. When the estimated payment rates are adjusted for health status, the estimated payment rate for Florida increases by nearly $65.00 a month; the rate for Puerto Rico increases a mere 70 cents per month.

As a result of Florida's higher cost structure and lower health status, plans that bid to serve all eligibles in a region that includes both Florida and Puerto Rico will have to submit a bid that includes beneficiary premiums and co-payments large enough to support the higher costs of doing business in Florida. The consequence will be that plans will be too expensive for the large majority of Medicare eligibles in Puerto Rico. Redistributions of higher average drug spending costs to a much lower per capita income population will be a significant problem inherent in any premium bidding scenario that requires Puerto Rico to be part of a multi-state region for purposes of structuring Part D premiums. The annual per capita income for residents of Puerto Rico was $8,185 according to the 2000 Census – far below the per capita income of Florida's $21,557

This problem is further complicated since the Commonwealth is provided a block grant to subsidize Part D premiums, co-pays and cost sharing of low income seniors as opposed to residents in Florida and the states who will receive low income subsidies as an entitlement. This fundamentally different structure for the low-income subsidy will create confusion and increase administrative errors for both the Medicare population and the insurance providers.

RTI contemplates that most of the bids for regional plans (either for MA or PDP regions) will come from organizations that are already participants in the local commercial market, who will then be attracted by the incentives in the statute to offer a PDP or, in the case of Medicare Advantage, expand to cover a larger regional market. Medicare beneficiaries living in the states and D.C. will likely enjoy the option of choosing coverage from a local plan with which they are familiar, and which is likely to know and include the beneficiary's providers in their networks. By contrast, local plans in the Commonwealth will be unwilling to bid to cover a region that includes a state (or states) with a much higher cost structure than Puerto Rico.

Therefore, beneficiaries living in Puerto Rico are unlikely to have the option of choosing a familiar, local plan if the Commonwealth is combined in a region with Florida or other states.

For all of these reasons, I strongly recommend that CMS establish a separate region for Puerto Rico for both MA Advantage plans and PDP plans in order to account for the unique circumstances in the Commonwealth. This approach is necessary for the effective implementation of the Part D program, and it is essential to ensure that the more than 600,000 Medicare beneficiaries residing in Puerto Rico will have the opportunity to take full advantage of the new drug benefit as intended by Congress.

I appreciate the opportunity to have provided these comments for the Committee's record, and I have included similar comments sent to myself, or to the Health and Human Services Department, for the record as well.

Sincerely,

Aníbal Acevedo-Vila
Resident Commissioner
Member of Congress

Colegio De Administradores De Servicios
De Salud De Puerto Rico

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August 12, 2004

Hon. Anibal Acevedo Vila
Puerto Rico-Resident Commissioner
US House of Representatives
126 Cannon HOB126 Cannon HOB
Washington, DC 20515-5401

Re: Comments on Options for Defining Regions for Medicare Advantage Regional Plans and Prescription Drug Plans under the Medicare Modernization Act of 2003

Dear Mr. Acevedo Vila

In relation with the Regional Medicare Advantage (MA) Preferred Provider Organizations (PPOs) and Prescription Drug Plans (PDPs) under the Medicare Modernization Act (MMA), CMS and its consultants, RTI International, are moving rapidly to recommend to CMS Administrator Mark McClellan and HHS Secretary Tommy Thompson a series of options for establishing between 10 and 50 Prescription Drug Plans (PDPs) and Physician Provider Organizations (PPOs) regions. Current CMS planning involves making Puerto Rico part of a Florida based region.

For Puerto Rico, the question of how to define the regions is very important as the final definitions may adversely affect the current health infrastructure in Puerto Rico and also affect many of the business decisions of physicians, insurance companies, such as Triple S and COSVI, managed care companies and hospitals and other Medicare Parts A and B providers, especially in future years.

Even more important, the decision can adversely affect the hard won right of Puerto Rico to ensure protection of its Spanish language, culture and customs, which are distinct and now fully recognized by Federal agencies, especially CMS. Furthermore, the question arises as to how will CMS ensure that the interest of rural seniors in Puerto Rico be protected in terms of choice if the PDP and PPO regions are based in Florida.

LEGISLATIVE BACKGROUND

The 2003 Medicare Prescription Drug and Modernization Act (MMA) establishes new prescription drug plans. The HHS Secretary is given discretion in establishing between 10 and 50 regions across the nation and the PDPs may conform to the PPO regions.

The MMA Conference Report allows CMS to determine where the Commonwealth of Puerto Rico and the Territories can fit in the construction of regions. Significantly, HHS/CMS has discretion to make Puerto Rico a stand alone based PDP and PPO region, and with Medicare data showing that Puerto Rico has 601,773 Medicare beneficiaries and 1.6 million Medicaid beneficiaries it clearly qualifies for its own stand alone region.

UNIQUENESS OF THE PUERTO RICO HEALTH CARE SYSTEM

Unmistakably, this MMA process to define PPO regions is consistent with a long tradition in which the Congress, HHS and CMS have failed to give sufficient consideration to the uniqueness of the health care infrastructure and special conditions in the Commonwealth of Puerto Rico and in The Territories, in general.

It appears that the emphasis here on defining regions is on the 50 States as usual. In this context, over the years the emphasis of Federal policymakers on uniform application of laws, regulations and policies, though well intended, have resulted in a litany of policy problems having unintended consequences, especially regarding Puerto Rico. This is due to a perennial failure to take into consideration the uniqueness of Puerto Rico.

Two examples of policy failures growing out of failure to heed special conditions in Puerto Rico would be HHS/HCFA implementation of the Medicare Prospective Payment System (PPS) in 1987 and the Medicare physician payment reform.

Puerto Rico, which has a population of 3.9 million, has a proven health care infrastructure that works effectively on behalf of its population.

Puerto Rico is unique in its relationship with the Medicare and Medicaid programs, not only as the largest United States self-governing territory, but also due to the Hispanic cultural orientation of its health care delivery system.

In the case of Medicare, Puerto Rico's health care system has a compelling case for its own region in that it has 601,773 Medicare beneficiaries. It thus has more beneficiaries than the usual threshold standard of 400,000 beneficiaries and more Medicare enrollees than the States of Connecticut, Arkansas, Colorado, Delaware, Kansas, Kentucky, Iowa, Mississippi, Oklahoma, Nebraska, Oregon, and West Virginia.

Even more important in relation to the magnitude of its Federal population which is little understood except amongst health experts and Think Tanks in Washington, DC, is that Puerto Rico has the fifth largest Medicaid population (1,620,616) of all States and Territories. Surprising to many, Puerto Rico's Medicaid program is larger than the big States of Massachusetts, Connecticut, New Jersey and Maryland.

Access to health care in Puerto Rico is significant and striking. In this regard, the term "access to care" has been defined as the ability of individuals or population groups to obtain needed medical services. In this respect, we are particularly proud of the access our health care system offers to our Medicare and Medicaid beneficiaries and to our vulnerable populations. This is because universal coverage exists in Puerto Rico. It reflects Puerto Rico's Spanish heritage and the importance placed on health care as a "right." To be sure, the Puerto Rican population has geographic and financial access to health care.

Significantly, in Puerto Rico geographical access is defined as 30 minutes or 39 miles from home. This standard is higher than in the continental United States. And our Commonwealth government has achieved all of this with a fiscal cap on Federal Medicaid expenditures, which Congress imposed on us in 1967.

In relation to the flow of our native population, historically migration to the States has provided a significant safety valve for our Island due to fluctuating economic downturns, with the majority migrating to New York, which has over one million Puerto Ricans, with a lesser number migrating principally to Chicago, Newark, New Jersey, and Hartford, Connecticut, and still even a smaller number going to Florida. However, that trend began reversing itself in 1971. In the years 1971-1975, migration to Puerto Rico from the Mainland added 143,000 native sons and daughters to the local society. This trend continues with "out" migration being at a much lower level than in the 1950's and 1970's. In all this, consider that our main cultural link to the Mainland is New York and not Florida.

CULTURE AND LANGUAGE CONSIDERATIONS

Puerto Rico, despite its close ties to the United States since 1898 and its familiarity to some Mainlanders, can be considered a foreign country in most respects. For instance, Puerto Rico's language and culture are distinctly Spanish and our attitudes towards family and work harks back to the European traditions.

Spanish is the dominant language in Puerto Rico, and the solid and upper middle class often gravitate towards English, making it easy to do business in Puerto Rico in terms of communication. Still, one faces a challenge in communication when interacting with the average Puerto Rican. For example, the economically deprived majority gravitates towards Spanish, not out of dislike for the English language but because of their poor command of it.

The question of fairness is a key concern relative to the criteria for defining a region. If Puerto Rico is placed in a State based PPO Region, we believe managed care organizations located in the Commonwealth of Puerto Rico would be clearly disadvantaged when competing with US companies to build provider networks outside of Puerto Rico. Not only are the language and cultural barriers significant but the capital needed to compete and develop viable delivery systems in the states would be arduous giving US domestic companies a material advantage due to resources and cultural ties and familiarity. Without a doubt, Puerto Rican companies would find it much more difficult to penetrate the Mainland health sector than US Companies opening up operations in Puerto Rico.

On the other hand, Puerto Rico's healthcare system has its own peculiarities, specially in the health insurance component. Many state companies that have ventured into our marketplace both in health insurance and information technology have failed because of cultural and language barriers. The most recent case was United Healthcare from Florida in their venture into the health reform program sponsored by the Government of Puerto Rico. Their failure after sustaining heavy losses in the managed care scenario created big problems for the government sponsored program since over 500,000 beneficiaries (medically indigent) were left uncovered.

Historically the above considerations, which also took into account the need for a new economic model (Operation Bootstrap), led to Puerto Rico's modern political system that began in 1952. This is when the Commonwealth of Puerto Rico was born with a new constitution and a new relationship with the United States. Since then, the Congress and Federal policymakers have tried diligently, though not always successfully, to recognize our unique differences and avoid taking legislative and policy steps that would wreck havoc with our health care infrastructure.

If CMS fails to address Puerto Rico's specific concerns, we foresee enormous customer service related issues down the road related to benefits and payments. Undeniably, the continued success of CMS' customer service program, which Puerto Rico Medicare providers have applauded publicly, depends upon a stable and familiar environment.

Definitely, we in Puerto Rico have been enormously impressed with the leadership of CMS over the past several years in assuring that Medicare beneficiaries receive culturally and linguistically appropriate services. CMS has taken considerable steps to ensure that health care, information and enrollment services furnished to beneficiaries under the Medicare and Medicaid programs are provided in an understandable and culturally competent manner. How will CMS ensure that Puerto Rico seniors will obtain the same level of linguistic services from a State based PPO region?

Under the current local system, Medicare beneficiaries in Puerto Rico have access to educational materials in Spanish relating to coverage of new benefits and ongoing program changes. Their questions are answered in Spanish.

Therefore, the College of Health Services Administrators of Puerto Rico urge you to support our stance that Puerto Rico be considered and approved by HHS/CMS as a separate stand alone regional plan for the PPOs/PDPs. It is critical that you support us on this vital matter.

Thank you for your continued support of Puerto Rico's health care community. We look forward to working with you to strengthen the health care system on which all Puerto Ricans rely.

Sincerely,

Marcos A. Reyes-Concepción, MHSA
President

Asociación de Hospitales de Puerto Rico
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August 3, 2004

The Honorable Aníbal Acevedo-Vilá
Puerto Rico-Resident Commissioner
US House of Representatives
126 Cannon HOB
Washington, DC 20515-5401

Dear Commissioner:

We are writing to enlist your help regarding our efforts to protect the integrity of the Puerto Rico health care infrastructure, as the Department of Health & Humans Services and the Centers for Medicare and Medicaid Services (CMS) move aggressively to implement the 2003 Medicare Prescription Drug and Modernization Act (MMA), and to specifically meet the Congressionally imposed statutory deadline of January 1, 2005, to conclude a market study establishing 10 to 50 Medicare Advantage regions.

For Puerto Rico the question of how to define the regions for the Prescription Drug Plans (PDPs) and Physician Provider Organizations (PPOs) is very important because the final definitions may adversely affect our current health care infrastructure, and also affect many of the business decisions of our Commonwealth Government as it provides drugs for our population and especially the health care delivery system for our physicians and insurance companies.

The Secretary of Health & Human Services was given wide discretion in establishing the 10 to 50 regions for the PDPs and PPOs, following the market survey mentioned above. However, our understanding is that CMS' preliminary analysis shows a basis for placing Puerto Rico in a State-based PPO, possibly Florida.

We are opposed to Puerto Rico being part of a State based PDP or PPO for a number of reasons. First, Puerto Rico has a proven health care infrastructure that has proven its effectiveness in service delivery to its 3.9 million population. Second, we believe a non-island PPO, in particular, would create enormous administrative and customer service problems for our 560, 725 Medicare beneficiaries, due to linguistic problems and a lack of orientation to our Hispanic health system.

The third reason and perhaps even more important, this MMA process to define PPO and PDP regions is consistent so far with a long tradition in which the Congress, HHS and CMS, though well intended, have failed to give sufficient consideration to the uniqueness of the health care infrastructure and special conditions in the Commonwealth of Puerto Rico and in The Territories, in general.

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Therefore, we urge you to support our stance that Puerto Rico be considered and approved by HHS/CMS as a separate stand alone regional plan for the PPOs/PDPs. It is critical that you support us on this vital matter.

Thank you for your continued support of Puerto Rico's health care community. We look forward to working with you to strengthen the health care system on which all Puerto Ricans rely.

Sincerely,

Jorge Torres, MHSA
Chairman
Puerto Rico Hospital Association

eo

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Enrique Baquero-Navarro, CHE
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August 4, 2004

The Honorable Aníbal Acevedo-Vilá
Puerto Rico-Resident Commissioner
United States House of Representatives
126 Cannon HOB
Washington, DC 20515-5401

Dear Commissioner Acevedo-Vilá:

We are writing to enlist your help regarding our efforts to protect the integrity of the Puerto Rico health care infrastructure, as the Department of Health & Humans Services and the Centers for Medicare and Medicaid Services (CMS) move aggressively to implement the 2003 Medicare Prescription Drug and Modernization Act (MMA), and to specifically meet the Congressionally imposed statutory deadline of January 1, 2005, to conclude a market study establishing 10 to 50 Medicare Advantage regions.

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The Secretary of Health & Human Services was given wide discretion in establishing the 10 to 50 regions for the PDPs and PPOs, following the market survey mentioned above. However, our understanding is that CMS' preliminary analysis shows a basis for placing Puerto Rico in a State-based PPO, possibly Florida.

We are opposed to Puerto Rico being part of a State based PDP or PPO for a number of reasons. First, Puerto Rico has a proven health care infrastructure that has proven its effectiveness in service delivery to its 3.9 million population. Second, we believe a non-island PPO, in particular, would create enormous administrative and customer service problems for our 601,773 Medicare beneficiaries, due to linguistic problems and a lack of orientation to our Hispanic health system.

The third reason and perhaps even more important, this MMA process to define PPO and PDP regions is consistent so far with a long tradition in which the Congress, HHS and CMS, though well intended, have failed to give sufficient consideration to the uniqueness

of the health care infrastructure and special conditions in the Commonwealth of Puerto Rico and in The Territories, in general.

Therefore, we urge you to support our stance that Puerto Rico be considered and approved by HHS/CMS as a separate stand alone regional plan for the PPOs/PDPs. It is critical that you support us on this vital matter.

Thank you for your continued support of Puerto Rico's health care community. We look forward to working with you to strengthen the health care system on which all Puerto Ricans rely.

Sincerely,

Enrique Baquero
Regent

COMMONWEALTH OF PUERTO RICO
Department of Labor and Human Resources
Right to Employment Administration

August 10, 2004

Honorable Anibal Acevedo Vilá
Resident Commissioner & Member of Congress
Commonwealth of Puerto Rico
126 Cannon HOB
Washington, DC 20515-5401

Dear Resident Commissioner Acevedo:

This letter's purpose is to express concern with the $91 million cut to state grants for employment services (ES) for fiscal year 2005 reported by the House Appropriations Committee on July 14.

Puerto Rico opposes this 12 percent cut in appropriations for ES state grants because the demand for services has exceeded the allocated funding for several years. Puerto Rico found it necessary to supplement its FY 2004 ES federal grant with **$ 2,663,740.00** in Reed Act Funds to address the needs of business and job seekers. During program year 2003-2004, **115,758** received the universal job seeker services available only through ES in Puerto Rico.

Businesses have come to rely on the ES to find the workers they need to remain competitive and assist in reducing the time former employees collect unemployment insurance (UI) helping to reduce their tax burden. A cut to ES will lead to more unemployment – as much as 7 more weeks for those not receiving services of unemployment for workers who will not receive ES assistance.

ES funds support the majority of the state's workforce system infrastructure, including staffing in the one – stop offices throughout the state. Puerto Rico will have to close local offices, freeze hiring of replacements, and lay off state employment service employees at a time when employers and workers alike need ES to find suitable job matches.

Puerto Rico believes labor exchange services rank with most effective government services provided. They lead to increased employment, reduce unemployment, lower unemployment taxes, and more taxes paid by workers earning more wages. There is no good reason to cut appropriations for labor exchange services.

Metro Building #5 Mayagüez Street, Corner Cidra Street, Hato Rey, Puerto Rico 00918 / Phone 754-5151
P.O. Box 364452 San Juan Puerto Rico 00936

Please restore the $91 million cut to the state grant for employment services. If you do, employers, workers and our state's economy will be better for your actions.

Thank you for your thoughtful consideration.

Sincerely,

María del Carmen Fuentes
Administrator
Commonwealth of Puerto Rico
Department of Labor and Human Resources
Right to Employment Administration

ASOCIACION MEDICA DE PUERTO RICO

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Ricardo Marrero Santiago, M.D.
Presidente

August 4, 2004

The Honorable Aníbal Acevedo-Vilá
126 Cannon
United States House of Representatives
Washington, DC 20515

Dear Congressman:

We are writing to enlist your help regarding our efforts to protect the integrity of the Puerto Rico care infrastructure, as the Department of Health & Humans Services and the Centers for Medicare and Medicaid Services (CMS) move aggressively to implement the 2003 Medicare Prescription Drug and Modernization Act (MMA), and to specifically meet the Congressionally imposed statutory deadline of January 1, 2005, to conclude a market study establishing 10 to 50 Medicare Advantage regions.

For Puerto Rico the question of how to define the regions for the Prescription Drug Plans (PDPs) and Physician Provider Organizations (PPOs) is very important because the final definitions may adversely affect our current health care infrastructure, and also affect many of the business decisions of our Commonwealth Government as it provides drugs for our population and especially the health care delivery system for our physicians and insurance companies.

The Secretary of Health & Human Services was given wide discretion in establishing the to 50 regions for the PDPs and PPOs, following the market survey mentioned above. However, our understanding is that CMS' preliminary analysis shows a basis for placing Puerto Rico in a State based PPO, possible Florida.

We are opposed to Puerto Rico being part of a State based PDP or PPO for a number of reasons. First, Puerto Rico has a proven health care infrastructure that has proven its effectiveness in service delivery to its 3.9 million population. Second, we believe a non-island PPO, in particular, would create enormous administrative and customer service problems for our 560,725 Medicare beneficiaries, due to linguistic problems and a lack of orientation to our Hispanic health system.

The third reason and perhaps even more important, this MMA process to define PPO and PDP regions is consistent so far with a long tradition in which the Congress, HHS and CMS, though well intended, have failed to give sufficient consideration to the uniqueness of the health care infrastructure and special conditions in the Commonwealth of Puerto Rico and The Territories, in general.

Our Puerto Rico Medical Association, by ways of our Delegation to the American Medical Association (AMA), strongly recommend this position that we know will be the best to our Medicare patients.

Therefore, we urge you to support our stance that Puerto Rico be considered and approved by HHS/CMS as a separate stand alone regional plan for the PPOs/PDPs. It is critical that you support us on this vital matter.

Thank you for your continued support of Puerto Rico's health care community. We look forward to working with you to strengthen the health care system on which all Puerto Ricans rely.

My best,

Ricardo Marrero Santiago, MD
President

September 28, 2004

The Honorable Charles E. Grassley
Chairman of the Senate Finance Committee,
Senate Committee on Finance
Attn: Editorial and Document Section
Rm. SD- 203
Dirksen Senate Office Bldg.
Washington, D.C. 20510 – 6200

Dear Senator Grassley:

The Kidney Care Partnership is pleased to submit its Statement for the Record for the Senate Finance Committee's September 14, 2004 hearing on "Implementing the Medicare Prescription Drug Benefit and Medicare Advantage Program: Perspectives on the Proposed Rules." In addition to our statement, we have attached a copy of the comments we submitted last week to the Centers for Medicare and Medicaid Services on Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2005.

Thank you for this opportunity to share our concerns with the Committee on the ESRD provisions of the Proposed Rule.

Sincerely,

K Means

Kathleen E. Means
President
Kidney Care Partners

Attachments

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Implementing the Medicare Prescription Drug Benefit and Medicare Advantage Program:
Perspectives on the Proposed Rules
Senate Committee on Finance
September 14, 2004

Statement for the Record
Kathleen E. Means, President
Kidney Care Partners
ADDRESS

Kidney Care Partners (KCP) is pleased to provide the Senate Committee on Finance with its Statement for the Record for the Committee's September 14, 2004 hearing on "Implementing the Medicare Prescription Drug Benefit and Medicare Advantage Program: Perspectives on the Proposed Rules." KCP is an alliance of members of the kidney care community that works with renal patient advocates, dialysis care professionals, providers, and suppliers to improve the quality of care for over 300,000 Americans with irreversible kidney failure, known as End Stage Renal Disease (ESRD).[1]

KCP also wishes to take this opportunity to thank Senators Conrad and Santorum for introducing S. 2614 the "ESRD Modernization Act of 2004." This important piece of legislation, which has bipartisan support in the Senate and House (the House version, H.R. 4927, was introduced by Representatives Camp, Jefferson, English, Neal, and Pomeroy), would establish an annual update framework for the ESRD composite rate, create public and patient education initiatives to increase awareness about chronic kidney disease (CKD), and provide Medicare coverage for CKD education services for Medicare-eligible patients. S. 2614 also would improve the home dialysis benefit, align incentives for physician surgical reimbursement for dialysis access to promote quality and lower costs, establish an outcomes-based ESDR reimbursement demonstration project, and evaluate the effect of the new Physician Fee Schedule G-code visit requirements for nephrologists. We hope that the provisions in S. 2614 as well as our comments today help to improve services to patients and ensure the economic stability of the ESRD program.

This statement reflects a more detailed set of comments which has been submitted to the Centers for Medicare and Medicaid Services (CMS) (see attached letter to Dr. Mark McClellan, CMS Administrator, dated September 24, 2004). The following abbreviated set of comments addresses the provisions of the Proposed Rule that directly impact the renal community and implement the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). To summarize, KCP believes:

- CMS Appropriately Increases the Composite Rate Based Upon the Requirements of MMA;
- CMS Miscalculates the Add-On to the Composite Rate;
- CMS Should Delay Implementation of the Basic Case-Mix Adjusted PPS;

[1] A list of Kidney Care Partners coalition members is included in Attachment A.

- CMS Should Consider Adjusting the Geographic Wage Index;
- CMS Should Revise Its Reimbursement Policy for Facilities with Exceptions To Comply with Congressional Intent; and
- Although CMS Proposes Needed Changes to Help Nephrologists Manage Their Patients, the Agency Should Allow Nephrologists to Bill for Venous Mapping.

Proposed 1.6% Increase in the December 31, 2004 Composite Rate

KCP members are pleased with the implementation of the 1.6 percent increase in the December 31, 2004 composite rate consistent with the requirements of MMA § 623. This increase is critically important to KCP members. The ESRD composite rate remains the only Medicare prospective payment system (PPS) without an annual update mechanism to adjust for changes in input prices and inflation. Over the years, dialysis providers have relied on increasing efficiencies to continue to provide quality care and improved treatment outcomes without an annual update in the composite rate. This progress can no longer be sustained.

The lack of an annual update presents a special challenge to dialysis providers. Overall labor rates, for example, went up seven percent between 2000 and 2001, according to MedPAC's 2003 report. Nursing salaries rose, on average, from $23,140 to $31,720 between 1992 and 2002, an increase of 27 percent, according to the U.S. Bureau of Labor Statistics. Dialysis centers cannot afford to compete for nurses and other professionals with health care providers that have PPS mechanisms with annual update formulas. To ensure that ESRD patients continue to have access to high quality care, the composite rate must be adjusted *annually* to cover dialysis providers' real costs. Given the critical need for the increase, it is essential that the agency correctly calculate the increase on the appropriate basis – the composite rate as of December 31, 2004.

The KCP members hope the increase will serve as a first step toward future modernization efforts, including a more institutionalized process that will recognize increases in the costs of providing care to seriously ill patients. We look forward to working with Congress and CMS to develop an annual update mechanism to ensure that the composite rate accurately reflects the cost of providing high-quality care to Medicare beneficiaries.

CMS Miscalculates the Add-On to the Composite Rate

CMS inappropriately establishes a single add-on adjustment that fails to recognize the real differences between the costs of hospital-based and independent facilities. The proposal to distribute drug margin attributable to and derived solely from free-standing dialysis facilities to hospital-based facilities is seriously flawed. Congress required CMS to establish the drug margin add-on payment to the composite rate to address concerns expressed by independent dialysis facilities that changes in the Part B reimbursement methodology for separately billed drugs would destabilize the free-standing renal community. A single add-on adjustment fails to recognize the significantly different reimbursement environment between hospital-based and independent facilities and Congress's intent to hold independent facilities harmless from drug payment reform changes that do not affect the hospital-based dialysis sector in the same material way. The hold-harmless provision is clearly meant to protect independent facilities from facing changes in payment that would result in reimbursement amounts less than their costs.

The hold-harmless language only makes sense if applied to take account of the different economic situations in which hospital-based and independent facilities find themselves. Simply put, the changes to 85 percent AWP or less do not affect hospital-based facilities, which are reimbursed based on a reasonable cost basis. Therefore, it is inconsistent with Congressional intent to establish a single add-on rate that is applied to both hospital-based and independent facilities.

CMS should apply the add-on adjustment, derived from independent facilities' acquisition cost data, to independent facilities only. Hospital-based facilities provide high-quality care to patients with ESRD and deserve to be adequately reimbursed, however, to combine these percentages into a single adjustment ignores the real differences that Congress has consistently recognized. By using a single add-on, CMS would be transferring part of the payments that previously went to independent facilities to hospital-based facilities. This exacerbates the very problem Congress sought to avoid.

The Calculation of the Add-On Factor Is Too Low

CMS should also increase the add-on percentage for very compelling policy and data-based reasons. The agency set forth a single adjustment of 11.3 percent that would apply to both hospital-based and independent facilities. Based upon analysis undertaken by The Moran Group, [2] this number underestimates by as much as **9 percent** the true difference between the payments for separately billed drugs (including erythropoietin) under the current system and the acquisition costs described by the Office of the Inspector General.

KCP has strongly urged CMS to use the data from the 2002 Outpatient 5 Percent Standard Analytical File to establish its base for calculating the add-on payment. Not only will it provide a more accurate calculation, but it also will help ensure that Congress's intent of holding facilities harmless from the changes to drug reimbursement methodology are fulfilled.

Updates to the Add-On Adjustment

KCP has proposed that CMS describe how it will update the add-on adjustment in the final rule because the proposed ASP-based payment system is not sustainable without update mechanisms. A central feature of implementing the add-on adjustment is how CMS will update it, consistent with the statutory requirements. Unfortunately, the Proposed Rule does not address this vital issue. The proposed system for 2005 is not sustainable and will further exacerbate the losses sustained by providers in delivering dialysis care to Medicare beneficiaries. CMS must provide information to the renal community about how the separately billed drug payments and add-on amounts will be updated before finalizing the rule. Therefore, KCP urged CMS to include a discussion and details of the update mechanism in the Final Rule and to provide interested parties with an opportunity to comment on it. Furthermore, this increase should be applied to reflect accurately any increases in acquisition cost.

The currently proposed ASP-3 percent "proxy" for the drug acquisition costs of dialysis facilities is not sustainable. First, it is based on a methodology that understates the true aggregate

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[2] The Moran Group, *Medicare Payment for Renal Dialysis Under Section 623 of the Medicare Modernization Act: Evaluation of CMS's Proposed Ratesetting Methodology*, 19 (Sept. 2004).

costs incurred by independent dialysis facilities associated with acquiring drugs. Second, the dynamic drug pricing changes that are occurring and will continue to occur under the broader Medicare Part B ASP-based drug payment reforms make projections based on an ASP-3% system unreliable. There is no basis for assuming that the acquisition cost relationships in the base snapshot taken by the OIG will continue to be reflective of the drug acquisition costs to be faced by facilities in 2005. Implicit in the budget neutrality concept is the expectation that CMS will reasonably project these payments to be made in 2005 and adopt a final drug margin add-on and drug payment approach that will fairly compensate facilities, and for that matter, not introduce distortions into the broader Part B drug payment reforms enacted by the Congress. More positively, CMS acknowledged this challenge in the preamble, although the option was not reflected in the actual proposal, by stating, "An alternative approach would be to use the 2003 acquisition prices from the OIG report, calculate the aggregate difference between such prices and payments for drugs under the AWP system, update this difference to 2005 and then apply the budget neutrality adjustment."

CMS Should Delay Implementation of the Case-Mix Adjusted PPS

Section 623(d)(1) of the MMA establishes a basic case-mix adjusted PPS. The case-mix approach proposed under the system is for a very limited number of patient characteristics. KCP members are extremely concerned about the proposed system. While we recognize that CMS may feel compelled by the statutory text to implement it by January 1, 2005, the Agency has the discretion to delay implementation until it has developed a system that works and does not place dialysis patients at risk by implementation of an inadequate and perhaps even unsound (certainly untested) case-mix methodology that could significantly redistribute Medicare financing in questionable ways. Indeed, while KCP members conceptually endorse sound, risk-adjusted payments, there are reasons to believe implementation of this particular model could generate the unintended result of being less than budget neutral, i.e. removing significant financing from the ESRD system over several years. CMS has discretion to delay implementation of the case-mix adjusted PPS and KCP has urged it to do so until it can significantly improve the methodological and operational aspects of the system.

A threshold concern of KCP members is that the Proposed Rule does not contain sufficient information to permit a full evaluation of the analysis upon which CMS relied when selecting these adjustors for the case-mix system. Given the importance of the analysis to the final policy, CMS should ensure that everyone interested in the regulations has access to the data needed to evaluate it independently. Even if CMS had had the appropriate data upon which to rely, the predictive value of the adjustors selected is questionable. Implementation of a system that inaccurately predicts the resources needed for patient care could adversely impact quality of care for this vulnerable population group.

In addition to the issues raised by the data and lack of predictability of the selected adjustors, implementation in 2005 is also problematic because of the lack of administrative resources available to ensure its appropriate application. First, current ESRD claims data and 2782 forms do not include sufficient information to implement either the peripheral vascular disease (PVD) or AIDS comorbidity adjustors. Second, even if CMS immediately modified the cost reports, it would be unlikely that providers would know whether their patients have PVD or AIDS. Currently, there is substantial disagreement as to how to define PVD.

The administrative problems associated with AIDS are even more troubling. Generally speaking, dialysis facilities, nephrologists, and other health care professionals within the renal community do not know whether a patient has been diagnosed with AIDS. Rather than ask, they rely upon dialysis center precautions outlined by the CDC to avoid exposing themselves and other patients to the disease. Knowing a patient's AIDS status is simply not necessary to providing him/her with dialysis treatments. In addition, strict state confidentiality laws enforce the practice of not asking patients if they have AIDS.

Because of the lack of predictability of the adjustors and the administrative difficulties associated with reporting them, implementing the case-mix system as proposed would contradict the desire of Congress to keep the system budget neutral. Instead, it would take away resources that would otherwise be directed toward patient care. Consistent with the problems described above, a substantial number of providers would not be able to code for the PVD and AIDS comorbidity adjustors when submitting claims. As a result, their reimbursement payments would be less than what they receive under the current system. Budget neutrality would be affected with the proposed case-mix adjusters resulting in a budget negative situation.

CMS Should Adjust the Geographic Wage Index

KCP members have urged CMS to adjust the geographic wage index. Unlike implementing the case-mix system, which requires complex methodological and administrative changes to the ESRD program, adjusting the geographic wage index is a much easier process. CMS should act to solve this problem now. The adjustment is necessary because the current geographic wage index is based on data that is twenty years old. The adjustment would not only be based upon new data, but also incorporate the Office of Budget and Management (OMB) definitions of Metropolitan Statistical Areas (MSA), Combined Statistical Areas (CSA), and "micropolitan."

CMS Should Revise Its Reimbursement Policy for Facilities with Exceptions To Comply with Congressional Intent

KCP is concerned that CMS proposes to require dialysis facilities with payment exceptions (i.e. pediatric dialysis centers) to choose between continuing to be paid at their exception rates and forfeiting their status by accepting the basic case-mix adjusted composite rate. If they select the former, they will not receive the Section 623 adjustments, including the add-on payment. This policy, in effect, eliminates the exception option by forcing facilities to accept lower payments for separately billed drugs if they remain part of the exception payment system. Therefore, KCP has urged CMS to permit facilities with exception rates to retain these rates and to receive the add-on adjustment to their payment so they, too, are held harmless from the changes to the reimbursement for separately billed drugs.

Venous Mapping:

KCP strongly supports CMS's proposal to establish a new G-code for venous mapping for hemodialysis access placement. However, as proposed, CMS would restrict the code to operating surgeons. This is not appropriate because, in most cases, non-surgical specialists, not surgeons, perform venous mapping as they are on the frontline of care for dialysis patients. We would hope that CMS revises its position and enables non-surgical specialists to use the new G-code for venous mapping.

KCP members sincerely appreciate the opportunity to express our concerns before the Senate Finance Committee and hope that CMS is responsive to the concerns we have expressed in the Final Rule. We look forward to working with Congress and CMS to successfully implement the ESRD provisions of the MMA.

September 28, 2004

The Honorable Mark McClellan
Administrator
Centers for Medicare and Medicaid Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: Comments on Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2005; Proposed Rule; CMS-1429-P

Dear Administrator McClellan:

Kidney Care Partners (KCP) is pleased to have the opportunity to provide the Centers for Medicare and Medicaid Services (CMS) with comments about the Proposed Rule for the Calendar Year 2005 Physician Fee Schedule (Proposed Rule).[1] KCP is an alliance of members of the kidney care community that works with renal patient advocates, dialysis care professionals, providers, and suppliers to improve the quality of care of individuals with irreversible kidney failure, known as End Stage Renal Disease (ESRD).[2]

In brief, our comments address the provisions of the Proposed Rule that directly impact the renal community and implement the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). To summarize, KCP believes:

- CMS Appropriately Increases the Composite Rate Based Upon the Requirements of MMA;
- CMS Miscalculates the Add-On to the Composite Rate;

[1] 69 Fed. Reg. 47488 (2004).

[2] A list of Kidney Care Partners coalition members is included in Attachment A.

Kidney Care Partners • 2550 M St NW • Washington, DC • 20037 • Tel: 202.457.5683

- CMS Should Delay Implementation of the Basic Case-Mix Adjusted PPS;
- CMS Should Consider Adjusting the Geographic Wage Index;
- CMS Should Revise Its Reimbursement Policy for Facilities with Exceptions To Comply with Congressional Intent; and
- Although CMS Proposes Needed Changes to Help Nephrologists Manage Their Patients, the Agency Should Allow Nephrologists to Bill for Venous Mapping.

I. Section 623: CMS Appropriately Increases the Composite Rate Based Upon the Requirements of MMA

KCP members are pleased with the implementation of the 1.6 percent increase in the December 31, 2004, composite rate consistent with the requirements of MMA § 623.

This increase is critically important to KCP members. The ESRD composite rate remains the only Medicare prospective payment system (PPS) without an annual update mechanism to adjust for changes in input prices and inflation. Over the years, dialysis providers have relied on increasing efficiencies to continue to provide quality care and improved treatment outcomes without an annual update in the composite rate. This progress can no longer be sustained. The lack of an annual update presents a special challenge to dialysis providers. Overall labor rates, for example, went up seven percent between 2000 and 2001, according to MedPAC's 2003 report. Nursing salaries rose, on average, from $23,140 to $31,720 between 1992 and 2002, an increase of 27 percent, according to the U.S. Bureau of Labor Statistics. Dialysis centers cannot afford to compete for nurses and other professionals with health care providers that have PPS mechanisms with annual update formulas. To ensure that ESRD patients continue to have access to high quality care, the composite rate must be adjusted annually to cover dialysis providers' real costs. Given the critical need for the increase, it is essential that the agency correctly calculate the increase on the appropriate basis – the composite rate as of December 31, 2004.

The KCP members hope the increase will serve as a first step toward future modernization efforts, including a more institutionalized process that will recognize increases in the costs of providing care to seriously ill patients. We look forward to working with the agency to develop an annual update mechanism to ensure that the composite rate accurately reflects the cost of providing high-quality care to Medicare beneficiaries.

II. Section 303: CMS Miscalculates the Add-On to the Composite Rate

A. CMS Inappropriately Establishes a Single Add-On Adjustment that Fails to Recognize the Real Differences between the Costs of Hospital-Based and Independent Facilities

CMS should not apply a single add-on adjustment for hospital-based and independent facilities. The proposal to distribute drug margin attributable to and derived solely from free-standing dialysis facilities to hospital-based facilities is seriously flawed. Congress required the agency to establish the drug margin add-on payment to the composite rate to address concerns expressed by independent dialysis facilities that changes in the Part B reimbursement methodology for separately billed drugs would destabilize the free-standing renal community. A single add-on adjustment fails to recognize the significantly different reimbursement environment between hospital-based and independent facilities and Congress's intent to hold independent facilities harmless from drug payment reform changes that do not affect the hospital-based dialysis sector in the same material way.

A single add-on adjustment contradicts Congressional intent. Congress has consistently recognized that there are differences between hospital-based and independent facilities by setting different payment methodologies for these different types of facilities. Congress required CMS to establish a different composite rate for hospital-based facilities than for independent facilities. The Social Security Act (SSA) requires that the composite rate differentiate between hospital-based facilities and other renal dialysis facilities. SSA § 1881(b)(7). CMS recognizes this in its regulations. 42 C.F.R. § 413.174(a)(1). Historically, this mandate has led CMS to set the composite rate for hospital-based facilities significantly higher than that for independent facilities to reflect presumed higher costs in hospital-based facilities that may have existed many years ago. For example, the hospital-based rate is approximately $132.41, while the amount for independent facilities $128.35. Although historically true, there is no statutory or regulatory requirement that the hospital-based facility composite rate actually be higher than the one for independent facilities. There is no support for the assumption that hospital-based facilities treat sicker patients than independent facilities.

Similarly, Medicare relies on different reimbursement methodologies for separately billed drugs for the different facility types. Prior to 2004, Medicare reimbursed independent facilities for these drugs using the lesser of the actual charge or 95 percent AWP. 42 C.F.R. §§ 405.701 & 413.174. For calendar year 2004, Medicare will continue to pay the lesser of actual charge or 95 percent AWP. *Id.* § 414.707(a)(2)(iv). In stark contrast, Medicare reimburses hospitals on a reasonable cost basis. *Id.* § 413.174. Related to this difference is the fact that hospital-based dialysis facilities do not file a separate cost report. Rather, they report costs on the hospital's overall cost report. This reporting difference makes it difficult to allocate and isolate the actual cost of dialysis in the hospital setting.

The difference in reimbursement methodology has led to significant differences in the payments facilities receive. MedPAC has consistently recognized that Medicare's payments to *independent* facilities for separately billed drugs "are subsidizing the lower payment margins under the composite rate." MedPAC, Report to Congress 102 (March 2002); *see also* MedPAC, Report to Congress 123 (March 2003).

Congress was well aware of the problem independent facilities face because of the inadequacy of the composite rate resulting in the need to cross-subsidize costs from separately billed drug payments. When it decided to change how Medicare reimburses for Part B drugs, Congress understood that it would negatively alter the payments to *independent* facilities for separately billed drugs, placing those facilities at risk of being reimbursed at less than their total costs for providing services to patients with ESRD.

In this context, Congress mandated that CMS provide an add-on payment to the composite rate that would essentially hold independent facilities harmless from any decrease in payments for separately billed drugs. MMA § 623. This language, which came from the Senate bill, was meant to ensure that there would be no change in the aggregate payments to independent facilities, as the summary of the Senate version of the bill in the Conference Report indicates:

> The composite rate for dialysis services furnished during 2004 would be increased by an amount to ensure that the sum of the total amount of the composite rate payments plus the payments that are billed separately for drugs and biologicals (but not EPO) would equal the composite rate payments plus payments made for separately billed drugs and biologicals (not including EPO) as if the drug pricing provisions of this legislation were not enacted.

H. Rpt. 108-391 684 (2003). The description of the conference agreement acknowledges the inclusion of the Senate language by noting that the overall spending for ESRD services should result in the same amount as if the previous system remained in place in 2005. *Id.* at 685.

The hold-harmless provision is clearly meant to protect independent facilities from facing changes in payment that would result in reimbursement amounts less than their costs. Congress knew when it reformed payments for drugs and biologicals that are not paid on a cost or prospective payment basis that it would also be changing how Medicare reimburses independent facilities for separately billed drugs. Even MedPAC has recognized as much in its most recent report by stating that the MMA reflects the concerns it has repeatedly expressed to Congress that "Medicare's policies do not appropriately pay for outpatient dialysis services." MedPAC Report to Congress 160 (March 2004).

The hold-harmless language only makes sense if applied to take account of the different economic situations in which hospital-based and independent facilities find themselves. Simply put, the changes to 85 percent AWP or less do not affect hospital-based facilities, which are reimbursed based on a reasonable cost basis. Therefore, it is inconsistent with Congressional intent to establish a single add-on rate that is applied to both hospital-based and independent facilities.

Given the differences between hospital-based and independent facilities recognized by Congress and MedPAC, CMS should apply the add-on adjustment, derived from independent facilities' acquisition cost data, to independent facilities only. CMS estimates that, if calculated separately, the add-on adjustment for hospital-based facilities would be 2.7 percent, while it would be 12.8 percent for independent facilities. The difference in percentages clearly demonstrates the effects of the different underlying reimbursement methodologies. Hospital-based facilities provide high-quality care to patients with ESRD and deserve to be adequately reimbursed; however to combine these percentages into a single adjustment ignores the real differences that Congress has consistently recognized. By using a single add-on, CMS would be transferring part of the payments that previously went to independent facilities to hospital-based facilities. This exacerbates the very problem Congress sought to avoid.

RECOMMENDATION: CMS should implement Congress's intent and provide the add-on adjustment to independent facilities.

B. The Calculation of the Add-On Factor Is Too Low

CMS should also increase the add-on percentage for very compelling policy and data-based reasons. The agency set forth a single adjustment of 11.3 percent that would apply to both hospital-based and independent facilities. Based upon analysis undertaken by The Moran Group[3], this number underestimates by as much as **9 percent** the true difference between the payments for separately billed drugs (including erythropoietin) under the current system and the acquisition costs described by the Office of the Inspector General.

To compute the add-on, CMS should have used *actual* 2002 ESRD drug spending amounts (obtainable from the Medicare 2002 Outpatient 5 Percent Standard Analytical File), rather than creating an *imputed* 2002 base derived from a pooled 10-quarter time series of data. CMS's base period assumption of drug spending is clearly lower than the actual 2002 utilization recorded in the 2002 Outpatient 5 Percent Standard Analytical File. If the actual 2002 data were used, the estimate of overall drug spending would rise by $257 million, or 9 percent. Assuming that the remainder of

[3]The Moran Group, *Medicare Payment for Renal Dialysis Under Section 623 of the Medicare Modernization Act: Evaluation of CMS's Proposed Ratesetting Methodology*, 19 (Sept. 2004).

the CMS methodology is correct, the alternative base would result in a higher percentage for the single add-on adjustment, taking it from 11.3 percent to 12.3 percent.

KCP strongly urges CMS to use the data from the 2002 Outpatient 5 Percent Standard Analytical File to establish its base for calculating the add-on payment. Not only will it provide a more accurate calculation, but it also will help ensure that Congress's intent of holding facilities harmless from the changes to drug reimbursement methodology is fulfilled.

RECOMMENDATION: CMS should rely upon actual 2002 drug claims data in its methodology for calculating the add-on adjustment.

C. CMS Should Describe How It Will Update the Add-On Adjustment in the Final Rule Because the Proposed ASP-Based Payment System Is Not Sustainable without Update Mechanisms

A central feature of implementing the add-on adjustment is how CMS will update it, consistent with the statutory requirements. Unfortunately, the Proposed Rule does not address this vital issue. The proposed system for 2005 is not sustainable and will further exacerbate the losses sustained by providers in delivering dialysis care to Medicare beneficiaries. CMS must provide information to the renal community about how the separately billed drug payments and add-on amounts will be updated before finalizing the rule. Therefore, KCP strongly urges the agency to include a discussion and details of the update mechanism in the Final Rule and to provide interested parties with an opportunity to comment on it.

Congress established an updating mechanism for the add-on payment in 2006 and beyond. First, in 2006, Section 623 requires CMS to calculate the add-on payment by determining the difference between the payment amounts for separately billed drugs and biologicals using 95 percent AWP and the acquisition cost or ASP methodology for the drugs. MMA § 623(d) (42 U.S.C. § 1395rr(b)(12)(C)(ii)). In 2007, CMS must adjust the add-on so that it incorporates separately billed drugs and biologicals for which there were no billing codes prior to January 1, 2004. MMA § 623(d) (42 U.S.C. § 1395rr(b)(12)(B)(ii)(B)). In addition, CMS must increase the case-mix PPS amount by applying the estimated growth in expenditures of separately billed drugs to the add-on component and convert that amount to an applicable increase beginning in 2006 and continuing in subsequent years. MMA § 623(d) (42 U.S.C. § 1395rr(b)(12)(F)). Congress envisioned this system to hold facilities harmless for dynamic changes in drug costs, as evidenced by the November 20, 2003, scoring report of the Congressional Budget Office, which concluded that there would be no savings attributable to these provisions. Based on a budget scoring analysis prepared for KCP by The Moran Company, it was estimated that using current methodology, without an appropriate update in place for 2006 and beyond, drug payments to providers (Medicare payments and beneficiary cost sharing) would be $ 855 million below acquisition costs over 2005 – 2014. Net of patient cost

sharing, this would produce savings to the Medicare program of approximately $ 615 million over this budget window

The way CMS implements the update will dramatically affect the quality of care for ESRD patients. KCP strongly encourages CMS to present its implementation strategy in a timely manner and to ensure that it is consistent with the mandates of Section 623. It is imperative that CMS include the mechanism in the Final Rule. The agency should describe the data it will use to update the drug portion of the prospective payment based on changes in the estimated growth in separately billed drugs. Additionally, this increase should be applied to reflect accurately any increases in acquisition cost.

Further, the currently proposed ASP-3 percent "proxy" for the drug acquisition costs of dialysis facilities is not sustainable. First, it is based on a methodology that understates the true aggregate costs incurred by independent dialysis facilities associated with acquiring drugs. Second, the dynamic drug pricing changes that are occurring and will continue to occur under the broader Medicare Part B ASP-based drug payment reforms make projections based on an ASP-3% system unreliable. There is no basis for assuming that the acquisition cost relationships in the base snapshot taken by the OIG will continue to be reflective of the drug acquisition costs to be faced by facilities in 2005. Implicit in the budget neutrality concept is the expectation that CMS will reasonably project these payments to be made in 2005 and adopt a final drug margin add-on and drug payment approach that will fairly compensate facilities, and for that matter, not introduce distortions into the broader Part B drug payment reforms enacted by the Congress. More positively, CMS acknowledged this challenge in the preamble, although the option was not reflected in the actual proposal, by stating: An alternative approach would be to use the 2003 acquisition prices from the OIG report, calculate the aggregate difference between such prices and payments for drugs under the AWP system, update this difference to 2005 and then apply the budget neutrality adjustment.

To ensure a sustainable system over the long-term, it is imperative that CMS describe more fully how it proposes to account for the changes that will occur in the drug acquisition costs facilities will face. Therefore, we feel very strongly that CMS must comply with the provisions governing acquisition costs and budget neutrality requirements by 1) updating the add-on payment on a regular basis so as to take reasonable account of these market dynamics, as well as the effects of broader Part B payment reform, 2) and do so in a manner consistent with the concepts and objectives evidenced in Section 1847A of the Social Security Act.

RECOMMENDATION: **CMS should propose and allow comment on its plan to implement the update to the drug component, which must include a mechanism to reflect changes in acquisition costs, in the Final Rule.**

III. Section 623: CMS Should Delay Implementation of the Case-Mix Adjusted PPS

Section 623(d)(1) of the MMA establishes a basic case-mix adjusted PPS. The case-mix approach proposed under the system is for a very limited number of patient characteristics. KCP members are extremely concerned about the proposed system. While we recognize that the agency may feel compelled by the statutory text to implement it by January 1, 2005, the agency has the discretion to delay implementation until it has developed a system that works and does not place dialysis patients at risk by implementation of an inadequate and perhaps even unsound (certainly untested) case-mix methodology that could significantly redistribute Medicare financing in questionable ways. Indeed, while KCP members conceptually endorse sound, risk-adjusted payments, there are reasons to believe implementation of this particular model could generate the unintended result of being less than budget neutral, i.e. removing significant financing from the ESRD system over several years.

A. CMS Has Discretion to Delay Implementation of the Case-Mix Adjusted PPS

Even though the statute indicates that the case-mix system should be in place by January 1, 2005, KCP strongly urges CMS to follow the path it has taken when developing other prospective payment systems to ensure that the system is accurate, predictive, and does not threaten quality of care. Specifically, the agency delayed implementation of the Hospital Outpatient PPS, as well as the Home Health PPS and the Skilled Nursing Facility PPS. When establishing these systems, CMS recognized the need for additional time beyond that allocated by Congress to ensure the development of an appropriate case-mix methodology that accurately predicted resource needs. The delay also provided the agency with more time to collect data and prepare each health care sector for implementation. Consistent with this historical approach, CMS should take the time it needs to get the system right. As described in detail below, if CMS were to implement the system as proposed, it would fail to meet the needs of the renal community because it is based upon an inaccurate methodology, is currently administratively infeasible to implement, and would negatively impact resources, thus jeopardizing patient care.

RECOMMENDATION: CMS should exercise its discretionary authority to delay implementation of the case-mix adjusted PPS until it can significantly improve the methodological and operational aspects of the system.

B. The Proposed Case-Mix Methodology Is Flawed Because Its Adjustors Are Not Accurate

To establish the case-mix system, CMS proposes adjustments based upon the patient characteristics of gender and age and the patient comorbidities of peripheral vascular disease (PVD)

and Acquired Immune Deficiency Syndrome (AIDS). KCP is concerned that these adjustors do not accurately predict cost variation among facilities.

CMS proposes adjustments based on gender and age. Noting that age and sex are routinely used in other risk adjustment schemas, CMS proposes to establish three age-based categories (under 65, 65-79, and over 80). Citing a report from the Kidney Epidemiology and Cost Center (KECC),[4] the preamble states that facilities treating patients in the younger and older categories have higher costs. CMS also proposes to include two comorbidity adjustors: PVD and AIDS.

A threshold concern of KCP members is that the Proposed Rule does not contain sufficient information to permit a full evaluation of the analysis upon which CMS relied when selecting these adjustors for the case-mix system. Given the importance of the analysis to the final policy, CMS should ensure that everyone interested in the regulations has access to the data needed to evaluate it independently.

The importance of providing the public with access to the underlying analysis is augmented by CMS's own admission that it does not have adequate data to evaluate fully all comorbidities. In fact, it remains uncertain whether the agency currently has sufficient data to examine the comorbidities that it did. For example, using data reported on *either* Form 2728 or from Medicare claims data for the *previous three years,* the KECC reported that the estimate of the incidence of PVD ranged from 58.6 percent to 70.2 percent of ESRD patients, depending on the type and location of facility. The estimate for AIDS incidence ranged from 1.3 percent to 4.4 percent.

As part of its consideration of the Proposed Rule, The Moran Group noted that data describing patient level cost is not available from current sources, which would make it difficult for the agency to impute these costs in a meaningful way. To establish the limited patient characteristics for the basic case-mix adjusted PPS, the preamble indicates that CMS relied upon Medicare claims history files and CMS Form 2728. Use of these data is problematic because they are non-contemporaneous data sources. The Moran Company also noted that conducting the regression analysis using facility-level average costs per treatment from cost reports rather than using patient-specific data is problematic and could seriously undermine any conclusions drawn from the information. Given these problems, it would seem more prudent for CMS to have first developed mechanisms to collect the necessary data upon which to base its analysis, to validate these data, and to work collaboratively with dialysis centers on this process.

Even if CMS had had the appropriate data upon which to rely, the predictive value of the adjustors selected is questionable. For example, KECC's analysis shows that the PVD and AIDS

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[4]Kidney Epidemiology and Cost Center, The University of Michigan, *Methodology for Developing a Basic Case Mix Adjustment for the Medicare ESRD Prospective Payment System* (2004).

adjustors are not statistically significant for 2002, but rather gained in significance only when three years of data are pooled. Based on the adjusted R-squared values, it appears that the control variables (variables not included as case-mix adjustors)[5] account for more of the variance in facility costs than the case-mix variables (*e.g.*, 32.4 percent as opposed to 0.6 percent) during the 2000-2002 pooled time period.

In addition, KECC's analysis demonstrates that application of the comorbidity adjustors to the composite rate does not result in substantial improvement in predictive value when evaluating adjustments using the 2000-2002 facility cost data. When the percent change due to the proposed implementation of the case-mix adjusted composite rate payments is calculated for 2000-2002, assuming complete reporting of PVD and AIDS status, none of the facility types would experience more than a 1.0 percent increase or decrease in their composite rate payment. According to KECC's analysis, independent facilities would experience a 0.14 percent increase and hospital-based facilities would experience a 0.29 percent increase in their composite rate payments. This analysis implies that the system would not function as it should, raising concerns about the potential negative impact of the proposed system on quality of care. Implementation of a system that inaccurately predicts the resources needed for patient care could adversely impact quality of care for this vulnerable population group.

RECOMMENDATION: CMS should delay implementation of the case-mix adjusted PPS system until a statistically valid system is developed that accurately aligns treatment costs with patient demographic and clinical characteristics.

C. Implementation of the Case-Mix System Should Be Delayed Because It Would Be Administratively Infeasible to Implement at this Time

In addition to the issues raised by the data and lack of predictability of the selected adjustors, implementation in 2005 is also problematic because of the lack of administrative resources available to ensure its appropriate application.

First, current ESRD claims data and 2782 forms do not include sufficient information to implement either the PVD or AIDS adjustors. The claims data contain primarily the patient's principal diagnosis. Because facilities do not regularly collect these data, there will be a substantial cost associated with the required changes in coding, billing, and claims submission processes if this system were to be implemented.

[5]Control variables included: skilled nursing facility wage index, a facility size variable, hospital-based vs. independent status, chain ownership for the six largest chains vs. smaller chains, and percent of Medicare patients with a urea reduction ratio greater than or equal to 65 percent.

Second, even if CMS immediately modified the cost reports, it would be unlikely that providers would know whether their patients have PVD or AIDS. Currently, there is substantial disagreement as to how to define PVD. To determine whether their actual records correspond to CMS estimates for PVD, KCP members examined their patient files. They concluded that the rates of PVD were substantially lower than the CMS estimates. Until the renal community can agree upon a definition, it will be administratively impossible to implement PVD as a predictive adjustor.

The administrative problems associated with AIDS are even more troubling. Generally speaking, dialysis facilities, nephrologists, and other health care professionals within the renal community do not know whether a patient has been diagnosed with AIDS. Rather than ask, they rely upon dialysis center precautions outlined by the CDC to avoid exposing themselves and other patients to the disease. Knowing a patient's AIDS status is simply not necessary to providing him/her with dialysis treatments.

Strict state confidentiality laws enforce the practice of not asking patients if they have AIDS. According to a recent survey conducted by Professor Lawrence O. Gostin at Georgetown University Law Center on behalf of the Centers for Disease Control and Prevention (CDC), virtually all states have enacted statutes to protect the confidentiality of individuals with HIV/AIDS.[6] At the time of the survey, thirty-eight states required a patient's informed consent before his/her HIV/AIDS status could be disclosed. For example, Massachusetts prohibited disclosure of HIV status without the patient's written consent, and New York and New Jersey also had stringent prohibitions on disclosure. Inappropriate disclosures subject the responsible party to criminal and/or civil penalties. Even KECC, which undertook the research to assist CMS with identifying the adjustors, noted that state laws could negatively impact the reporting of AIDS status. In its own analysis, it excluded seven to eight percent of the data in part because state confidentiality laws restricting the reporting of AIDS made the data unusable.

Having facilities report their AIDS data in the aggregate is not a viable solution either. As the Federal Standards for Privacy of Individually Identifiable Health Information (the HIPAA Privacy Regulation) recognize, disclosing health information that contains only a few identifiers can often lead to the identity of the patient being disclosed, especially in areas with smaller populations. Even if all identifiers are stripped, reporting that includes age, race/ethnicity, gender, and other factors used in "small cell size reporting" remains problematic. For example, the Health Resources and Services Administration (HRSA) restricts reporting AIDS along with these factors on small cell reporting because of the risk of disclosure. Given the fact that CMS's proposed adjustors also

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[6]Lawrence O. Gostin, Zita Lazzarini, and Kathleen M. Flaherty, *Legislative Survey of State Confidentiality Laws, with Special Emphasis on HIV and Immunization*, Final Report presented to the U.S. Centers for Disease Control and Prevention (1996).

include age and gender, the concerns raised by the HIPAA Privacy Regulation and the HRSA policy would exist with the case-mix reporting as well.

If providers are unable to report the characteristics of their unique patient profile, then the case-mix adjustors will not be accurate facility-specific measures but rather an approximation of their patient profile. This alternative would expose providers to substantial fraud and abuse liability if they could not provide the proper documentation upon request to federal and/or state officials.

RECOMMENDATION: CMS should refrain from relying on adjustors that cannot be easily known by providers.

D. If Implemented as Proposed, the Case-Mix System Would Negatively Affect Resources Needed to Treat Patients

Because of the lack of predictability of the adjustors and the administrative difficulties associated with reporting them, implementing the case-mix system as proposed would contradict the desire of Congress to keep the system budget neutral. Simply put, it would take away resources that would otherwise be directed toward patient care. Consistent with the problems described above, a substantial number of providers would not be able to code for the comorbidity adjustors when submitting claims. As a result, their reimbursement payments would be less than what they receive under the current system. The Moran Group modeled the potential impact of PVD and AIDS coding issues on total ESRD reimbursements under three sets of assumptions.

EFFECTS OF NON-CODING OF COMORBIDITIES[7]

	Assumed Percentages of the Population		
HIV/AIDS	1.0%	2.0%	3.0%
Peripheral Vascular Disease	9.0%	13.0%	17.0%
All other	90.0%	85.0%	80.0%
Reimbursement Effect of Non-Coding	-0.77%	-1.20%	-1.60%

The effect of non-coding ranges from –0.77 percent to –1.6 percent, depending upon the incidence of PVD and AIDS. As The Moran Group's analysis shows, the administrative problems described above will lead to a system that actually decreases overall payments for ESRD. This clearly contradicts Congress's express intent that CMS design a system that is budget neutral and the CBO estimates that the case-mix system would not result in savings. MMA § 623; CBO, November 20, 2003 Estimates of the MMA.

RECOMMENDATION: **CMS should rely upon the discretion it has used in the past to delay implementation of the case-mix adjusted PPS so that it can ensure that it has established the appropriate methodology, has the data it needs, and has worked collaboratively with the renal community on implementation.**

IV. Section 623: CMS Should Adjust the Geographic Wage Index

KCP members strongly urge CMS to adjust the geographic wage index. Unlike implementing the case-mix system, which requires complex methodological and administrative changes to the ESRD program, adjusting the geographic wage index is a much easier process. CMS should act to solve this problem now.

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[7]Source: The Moran Group, *Medicare Payment for Renal Dialysis Under Section 623 of the Medicare Modernization Act: Evaluation of CMS's Proposed Ratesetting Methodology* 19 (Sept. 2004). Average Case Mix, All Facility Types using CMS Weights 1.1919.

The adjustment is necessary because the current geographic wage index is based on data that is twenty years old. The adjustment would not only be based upon new data, but also incorporate the Office of Budget and Management (OMB) definitions of Metropolitan Statistical Areas (MSA), Combined Statistical Areas (CSAs), and "micropolitan." Congress recognized the need for such an update and directed CMS to adjust the geographic wage index. MMA § 623(d). Additionally, MedPAC has recommended that CMS update its information on wage rates in different markets by occupation and provider type. MedPAC, Report to the Congress (March 2001).

KCP members suggest that CMS implement the adjustment as follows. Within 180 days, the agency should report on the impact of implementing an adjusted geographic wage index and include a transition plan. The adjusted index should apply the OMB definitions of MSAs, CSAs, and "micropolitan" to the dialysis community in a manner that is consistent with the agency's methodology for hospitals. The transition period should not exceed two years.

RECOMMENDATION: CMS should update the geographic wage index for the ESRD applying the new OMB definitions and in a manner consistent with the intent of Congress and MedPAC's recommendation.

V. Section 623: CMS Should Revise Its Reimbursement Policy for Facilities with Exceptions To Comply with Congressional Intent

KCP applauds CMS for maintaining the ESRD composite rate exception and is extremely pleased that Congress restored the exception for pediatric facilities. We are concerned, however, that the agency proposes to require dialysis facilities with payment exceptions to choose between continuing to be paid at their exception rates and forfeiting their status by accepting the basic case-mix adjusted composite rate. If they select the former, they will not receive the Section 623 adjustments, including the add-on payment. 69 Fed. Reg. at 47535. This policy in effect eliminates the exception policy by forcing facilities to accept lower payments for separately billed drugs if they remain part of the exception payment system. Therefore, KCP strongly urges CMS to permit facilities with exception rates to retain these rates and to receive the add-on adjustment to their payment so they too are held harmless from the changes to the reimbursement for separately billed drugs.

By not adjusting their exception rates to hold them harmless from changes to the Part B drug reimbursement methodology, CMS is thwarting Congress's clear intent to protect these facilities. Congress signaled its desire to protect these facilities originally in the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA), Pub. Law. 106-544, Appendix F, § 422(a)(2). The restoration of the pediatric facilities exception in the MMA demonstrates Congress's desire to maintain the exception rates program as well. MMA § 623(b). Congress also sought in the MMA to protect *all* independent facilities from the negative

reimbursement implications of changes to the Part B drug reimbursement methodology by establishing an add-on component to the new case-mix adjusted PPS. MMA § 623(d)(12)(B)(ii).

This language indicates that Congress clearly understands that some facilities will experience higher costs than others and that there should be exception rates for facilities that meet the requirements set forth by CMS. The purpose of these exceptions is to allow facilities faced with legitimate utilization trends that result in higher allowable costs per treatment to receive payments that are greater than the composite rate. To ignore the fact that the reimbursement methodology changes for separately billed drugs will lower the overall reimbursement for these facilities disregards Congressional intent. CMS has discretion as to how it structures the exception rates. SSA § 1881(b)(7). We suggest it use this discretion to provide facilities with exception rates the same add-on adjustment that is part of the case-mix adjusted composite rate to ensure that Congress's intent to hold dialysis facilities harmless from the Part B changes is fulfilled.

RECOMMENDATION: CMS should provide facilities that receive exception rates with the same add-on adjustment that is part of the case-mix adjusted composite rate.

VI. Although CMS Proposes Needed Changes to Help Nephrologists Manage Their Patients, the Agency Should Allow Nephrologists to Bill for Venous Mapping

A. CODING—TELEHEALTH: CMS Should Maintain ESRD-Related Services as Part of Medicare's Telehealth Services

KCP members appreciate the expansion of Medicare's telehealth services to include ESRD-related services with two or three visits per month and ESRD-related services with four or more visits per month. This change will especially benefit patients who live in Health Professional Shortage Areas (HPSAs) and the nephrologists who care for them by providing an alternative means of visiting with them.

RECOMMENDATION: CMS should retain the revision to telehealth services in the Final Rule.

B. CODING—VENOUS MAPPING: CMS Should Allow Nephrologists to Bill for Venous Mapping and Revise the Proposed Rule so that the Appropriate Type of Codes Are Used

KCP strongly supports CMS's proposal to establish a new G-code for venous mapping for hemodialysis access placement. However, we encourage the agency to make some important modifications to maximize the benefits of this change for patients.

Venous mapping is critically important to patients since it ensures high quality dialysis. In most cases, non-surgical specialists, not surgeons, perform venous mapping because they are on the frontline of care for dialysis patients. As proposed, CMS would restrict the code to operating surgeons. If maintained, the restriction would limit the ability of patients to receive this important service. In addition, to maximize the effectiveness of this service, it is important that Medicare reimburse providers for it regardless of whether placement subsequently occurs. The minimal costs of the procedure are outweighed by the potential savings that result from fewer hospitalizations and the improvement in quality of care.

RECOMMENDATION: CMS should modify the venous mapping policy to ensure that all patients can access this important procedure.

C. MANAGING PATIENTS ON DIALYSIS: As Proposed, CMS Should Maintain Its Commitment To Count Observational Visits as Visits for Purposes of Billing the Monthly Capitation Payment

KCP members are pleased that CMS proposes to include the observation setting among the sites-of-service in which the G-code visits can be provided. This change reflects the reality of how physicians care for their patients on dialysis. However, it remains unclear how nephrologists from a different practice or location should bill for dialysis-related physician services provided to patients in the observation setting. We suggest that these physicians or physician extenders be permitted to use CPT code 90935, hemodialysis, one evaluation, for these services.

RECOMMENDATION: CMS should retain this modification and clarify how nephrologists from different practices/locations can bill for these services.

D. MANAGING PATIENTS ON DIALYSIS: It Is Appropriate for CMS To Change the Descriptions of Relevant G-codes To Account for Issues Related to Providing ESRD-Related Services to Transient Patients and for Partial Month Scenarios

KCP supports CMS's decision to revise the G-codes and address the gaps in payment for partial month payment scenarios. This change will provide a consistent way to bill for transient patients, home patients, and those situations in which a patient is hospitalized, receives a transplant, or dies before a physician or physician extender could complete an assessment.

We suggest that CMS also include all situations in which a nephrologist or physician extender performs a visit with a dialysis patient, regardless of the status of the complete assessment, so that physicians may be considered for reimbursement in these instances. Although we appreciate that CMS seeks to ensure that every dialysis patient receives a complete assessment each month, there are more appropriate ways to encourage this practice than by prohibiting physicians from seeking reimbursement for providing specific services to patients and incurring practice expense and professional liability costs.

Finally, we suggest that rather than identify patients as "transient," CMS refer to them as "visiting." This nomenclature avoids the pejorative connotations of the term "transient." Similarly, we suggest defining a "visiting patient" as "a patient receiving dialysis or renal-related care whose care is temporarily supervised (for less than one month's time) by a physician who is not a member of the practice that usually charges under the MCP or G codes."

RECOMMENDATION: CMS should slightly expand this modification to the G-codes and revise the language related transient patients.

VII. Conclusion

KCP members sincerely appreciate your review of our concerns and look forward to working with the agency on implementing the MMA. Please do not hesitate to contact Kathy Means at 202-457-6328 if you have questions regarding these comments.

Sincerely,

Kathleen E. Means
President
Kidney Care Partners

Attachments

Attachment A – Kidney Care Partners Coalition Members

Abbott Laboratories
Aksys, Ltd.
American Kidney Fund
American Nephrology Nurses Association
American Regent, Inc.
Amgen
Baxter Healthcare Corporation
Bone Care International
California Dialysis Council
Centers for Dialysis Care
DaVita, Inc.
Fresenius Medical Care North America
Gambro Healthcare/USA
Genzyme
Medical Education Institute
National Kidney Foundation
National Renal Administrators Association
Northwest Kidney Centers
Physicians Dialysis, Inc.
Renal Care Group
Renal Physicians Association
Renal Support Network
Satellite Health Care
Sigma-Tau Pharmaceuticals, Inc.
Watson Pharma, Inc.

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Our mission is to improve the quality of life for people who have psoriasis and psoriatic arthritis. Through education and advocacy, we promote awareness and understanding, ensure access to treatment and support research that will lead to effective management and, ultimately, a cure.

September 23, 2004

Senate Finance Committee
Attn. Editorial and Document Section
Room SD-203
Dirksen Senate Office Building
Washington, DC 20510-6200

Dear Senate Finance Committee:

Thank you very much for the opportunity to include the views of the National Psoriasis Foundation in the record of the September 14, 2004 Senate Finance Committee hearing entitled "Implementing the Medicare Prescription Drug Benefit and Medicare Advantage Program: Perspectives on the Proposed Rules."

Enclosed is the statement of the Psoriasis Foundation. We would be happy to provide an electronic copy via email if you require that.

The National Psoriasis Foundation is the leading U.S. nonprofit organization working to improve the quality of life of over 5 million Americans with psoriasis and/or psoriatic arthritis. The Foundation connects patients with each other, funds research, produces educational materials, advocates for patients who face disability, insurance, discrimination, and other challenges, works to shape public policy, and more.

Please contact me at 800.723.9166 xt 367, 503.546.8367, or *rgassner@psoriasis.org* if you have any questions. Thank you.

Sincerely,

Robert Gassner
Director of Advocacy

enclosure

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New York, N.Y.

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Chairman, Medical Board
New York, N.Y.

Statement of the National Psoriasis Foundation for the United States Senate Committee on Finance hearing on "Implementing the Medicare Prescription Drug Benefit and Medicare Advantage Program: Perspectives on the Proposed Rules" September 14, 2004

Thank you for the opportunity to present these comments to the Committee on Finance.

A recent study estimated that there are more than 800,000 Americans age 65 or older with psoriasis, and nearly 1.5 million 55 or older with the disease.[1] One-third of those older Americans have what is considered moderate to severe psoriasis, which often requires systemic medications. These Americans are part of the present and future Medicare population who most need a prescription drug benefit, and we would like to share our thoughts about how a prescription drug benefit, done right, can lead to healthier older Americans and even lower total health care costs.

Psoriasis is a lifelong skin disease that occurs when faulty signals in the immune system cause skin cells to regenerate too quickly— every three to four days instead of the usual 30-day cycle. Extra skin cells build up on the skin's surface, forming red, flaky, scaly lesions that can itch, crack, bleed and be extremely painful. Psoriasis generally appears on the elbows, knees, limbs and scalp but it can appear anywhere on the body, covering some people from head to toe. The Food and Drug Administration reports that psoriasis has two peaks of occurrence, one at 20-30 years of age and one at 50-60 years of age, indicating that while some patients have faced psoriasis for decades by the time they are eligible for Medicare, others are grappling with a relatively new disease at that time.[2]

In addition to skin symptoms, about one quarter of psoriasis patients have also been diagnosed with psoriatic arthritis, a degenerative disease of the joints and connective tissues associated with psoriasis, and similar to rheumatoid

[1] Stern et al., "Psoriasis Is Common, Carries a Substantial Burden Even When Not Extensive, and Is Associated with Widespread Treatment Dissatisfaction," Journal of Investigative Dermatology Symposium Proceedings, March 2004. The study used national survey data commissioned by the National Psoriasis Foundation.

[2] "Background for Advisory Committee Meeting to Discuss Oral Tazarotene for the Treatment of Moderate to Severe Psoriasis," Food and Drug Administration, July 2004.

arthritis. A 1999 study found that psoriasis can cause reductions in physical and mental functioning comparable to that seen in diabetes, heart disease, hypertension, and depression.[3]

Treatments for moderate to severe psoriasis present patients with difficult trade-offs. While several treatments are effective for many patients in controlling their symptoms, these treatments often carry the risk of serious side effects. For example, methotrexate, an anti-cancer drug that has been used to treat moderate to severe psoriasis since the 1950s, can be toxic to the liver, particularly in patients who consume alcohol. Even on the relatively low doses used for psoriasis, some patients die from taking the drug.

Cyclosporine clears most psoriasis patients, but also causes kidney damage in most patients, limiting its use to one year— not much help for a lifelong disease. "PUVA," which combines ultraviolet light (UVA) and the drug psoralen, can increase carcinomas and possible melanoma. And an oral retinoid like acitretin can cause bone changes and organ damage. Finally, the relatively safe treatment of ultraviolet light "B" (UVB) often requires three doctor's office visits per week for months, which can be a challenge for some older Americans.

In the last two years, the FDA has approved three new "biologic" medications for psoriasis, and one has been approved for psoriatic arthritis. Others are in advanced clinical trials. These drugs, so far, appear to be free from some of the dangerous side effects of older medications, although long-term side effects will not be known for many more years. These drugs, however, are relatively expensive, and like all psoriasis medications, they do not work for everyone.

The bottom line for psoriasis patients today is that no treatment works for everyone, some treatments work for a while then lose effectiveness over time, all treatments carry a unique set of side effects, and newly-approved treatments are also currently the most expensive. This presents a challenging situation for patients and their physicians.

For these reasons, it is essential that Medicare beneficiaries have access to the full range of psoriasis therapies, so they, in conjunction with their physician, can use the treatments that are most appropriate for them. The Psoriasis Foundation urges United States Pharmacopeia (USP) to create Model Guidelines that do not discourage access to this full range of options. We also urge the Centers for Medicare and Medicaid Services (CMS) to direct prescription drug plan sponsors and Medicare Advantage organizations to offer psoriasis and psoriatic arthritis patients this full range of treatment options at reasonable prices.

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[3] Rapp et al., "Psoriasis causes as much disability as other major medical diseases," Journal of the American Academy of Dermatology, September 1999.

The Psoriasis Foundation also urges CMS to guard against harmful utilization management strategies. Right now across the country, prohibitive cost sharing and inappropriate step therapy and unnecessary prior authorization requirements are unfairly hurting psoriasis patients. This should not be allowed to carry over into this new Medicare benefit.

With specific attention to the Draft Model Guidelines developed by USP, the Psoriasis Foundation has the following suggestions:

- We applaud the proposed creation of a category called "antipsoriatics" (Line 51), but believe the proposed classes use language that is inadequate and confusing. An approved therapy could fit into more than one suggested class. Some approved therapies might be left out entirely because only a minimum of two drugs is required in each class. As described above, the various therapies for psoriasis are distinct in their effectiveness and side effects, so access to the full range of therapies is necessary in order to meet the medical standard of care.

- The category "antipsoriatics" should include several more classes in a way that accommodates all of the following types of treatments: Vitamin D analogues (topical), retinoids (topical and oral), immunomodulators (e.g., corticosteroids), immunosuppressants (e.g., cyclosporine), calcineurin inhibitors, antiproliferative agents (e.g., coal tar), phototherapy agents, TNF inhibitors, and T-cell mediators.

- We are concerned about the "recommended" nature of the subdivisions. Will some formularies simply be allowed to leave out subdivisions, and effective therapies, entirely? For example, psoralen (Line 104) is essential to "PUVA" phototherapy.

- We recommend that the Guidelines recognize TNF inhibitors (Line 126) as a distinct pharmacologic class rather than a subdivision, and also include a pharmacologic class called "T-cell mediators". TNF inhibitors (e.g., etanercept, others in development) and T-cell mediators (e.g., alefacept, efalizumab, others in development) are major advances for treatment of psoriasis or/and psoriatic arthritis. As with the other drugs mentioned above, they each have different clinical effects and safety profiles and are therefore appropriate for certain patients and not for others. They are also currently available on many formularies.

With regard to the formularies that will be developed using the Guidelines:

- We trust formularies will not limit the possibilities for various combination therapies. This is a standard of care that applies to many patients, not just those with psoriasis.

- If the formularies limit access to therapies for psoriasis or psoriatic arthritis, this will discourage many people, particularly patients with moderate to severe psoriasis and/or psoriatic arthritis, from enrolling in the Medicare drug benefit. This may be seen as discriminatory and could hamper implementation of the benefit. For example, only one drug is FDA-approved with a specific indication for psoriatic arthritis. A formulary that did not offer this drug would be inadequate.

- We also hope the guidelines will lead to formularies that provide flexibility for patients and physicians. This is particularly important for people with chronic conditions, who have a high incidence of comorbidities.

Finally, the Psoriasis Foundation supports and strongly encourages CMS to consider carefully the comments on the Medicare Prescription Drug Benefit proposed rules that the National Health Council will submit soon.

The Medicare Prescription Drug Benefit that begins in 2006 will offer older Americans an historic opportunity to improve their health. We applaud lawmakers for recognizing the need to include a prescription drug benefit within Medicare. We look forward to working with Congress, CMS, and USP to make sure that the program fulfills its promise to Medicare beneficiaries with psoriasis and psoriatic arthritis.

About the National Psoriasis Foundation

The National Psoriasis Foundation is the leading nonprofit organization fighting to improve the quality of life of the more than 5 million Americans diagnosed with psoriasis and/or psoriatic arthritis and their families. Its mission is to educate people about these diseases and their treatments, raise public awareness, and support ongoing research. The organization is headquartered in Portland, Ore. For more information, please call the Psoriasis Foundation at 800.723.9166 or visit *http://www.psoriasis.org*

UnitedHealth Group

STATEMENT FOR THE RECORD
RICK JELINEK, PRESIDENT
SENIOR AND RETIREE SERVICES
UNITEDHEALTH GROUP

U.S. SENATE COMMITTEE ON FINANCE
SEPTEMBER 14, 2004

Implementing the Medicare Prescription Drug Benefit and Medicare Advantage Program:
Perspectives on the Proposed Rule

Today, the U.S. Senate Finance Committee is examining CMS's proposed regulations to implement the Medicare drug benefit and the Medicare Advantage program. I am pleased to have this opportunity to submit for the record my views on the appropriate size of the Medicare Advantage regions.

I believe that for Medicare Advantage regional PPOs, large, multi-state regions are important to the success of the Medicare Modernization Act (MMA), especially in providing access to beneficiaries in rural areas. It is my strong conviction that 50 single-state regions would merely reflect the status quo, and the status quo has not created a vibrant, consumer-driven Medicare program that provides broad-based access to affordable, high quality care. Large, multi-state regions for the PPO offering are the best way to reach the most people, including those in rural and other areas traditionally underserved by coordinated health care financing and delivery models. Single-state regions do not provide incentives to participate in underserved areas, nor to keep intact existing metropolitan service areas that cross multiple state borders.

However, the size of the regions is only part of the equation in making regional PPOs a success. In particular, the following two issues are relevant to the program's success:

- First, we believe that beneficiaries located in rural areas with a limited selection of health care services providers may not have access to regional PPOs if the provider and the regional carrier are unable to agree on terms for a contract. To ensure

choices for beneficiaries in parts of the region where there is a limited supply of providers, those providers who accept patients in traditional Medicare should not be permitted to discriminate against patients who choose the regional plan.

- Second, we want to work with CMS and Congressional leaders to examine ways to level the competitive playing field between regional PPOs and local Medicare Advantage offerings. In particular, premium and benefit flexibility within a region may be necessary for regional PPOs to address the issue of cost disparities between urban and rural geographies within that particular region.

I greatly appreciate your leadership on these issues and look forward to working with you to improve the affordability and value of the Medicare program specifically in advancing the health and well-being of covered beneficiaries.

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